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1       SCIENTIFIC REVIEW PANEL  
2       Irvine, California  
3       Thursday, March 19, 1992  
4       10:45 a.m.

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- - P R O C E E D I N G S - -

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10               CHAIRMAN PITTS: Good morning. We're here  
11       today to discuss a number of items actually. The first on  
12       the agenda is to consider the identification of  
13       1,3-butadiene as a toxic air contaminant. We had met once  
14       before on this subject and now this second. Since that  
15       meeting we have been provided with some alterations and  
16       additions and considerations that are relevant to the final  
17       decisions of the Panel.

18               So we'll begin now with Part A, and  
19       Ms. Shiroma will start the ball rolling.

20               MS. SHIROMA: Thank you, Dr. Pitts.

21               CHAIRMAN PITTS: Along with the NCAA playoffs  
22       who will start the ball rolling tonight, right?

23               Okay, would you please start.

24               MS. SHIROMA: Sure. And just in brief, the  
25       Panel at the last meeting basically finished the discussion

1 of the Part A and provided us with some instructions to  
2 provide clarification on certain aspects of the Part A.  
3 And I believe that we provided that to you in the material  
4 that we sent you.

5 In the meantime, we're here if you have any  
6 other questions about either the Part A or the material  
7 sent to you. We also have Dr. Melanie Marty, Joseph Brown,  
8 and also David Holtzman here to finish your discussion of  
9 the Part B. Basically you folks were somewhat near the end  
10 but hadn't completed that discussion at the last meeting.  
11 So they're here to go ahead and finish that for you.

12 CHAIRMAN PITTS: So should we start on Part A?

13 MS. SHIROMA: If you have any questions on  
14 Part A.

15 CHAIRMAN PITTS: Yes, we have just a few  
16 questions, I think. I'll go through the Panel.

17 And Kelly and Joan, why don't you come up and  
18 we'll start. Let me just assemble this.

19 Do Panel Members have any questions that you'd  
20 like to bring up in terms of Part A and in terms of the  
21 proposed revisions that Genevieve sent to us a while back?  
22 And indeed Part A and B are in this document of March 4th  
23 that was sent to Panel Members.

24 So we'll just go around, and I'm opening it up  
25 for questions -- and on the Executive Summary, because we

1       have a couple on the summary.

2               MS. SHIROMA: Yes, that's right.

3               CHAIRMAN PITTS: Okay. Well, shall we just  
4       start with the Executive Summary?

5               MS. SHIROMA: These are described in the first  
6       three pages of the material sent to you on March 4th. So  
7       the changes we propose are on page 1, there are four  
8       bullets there.

9               CHAIRMAN PITTS: Okay, this is page 1 of the  
10      changes, right?

11              MS. SHIROMA: Yes, that's correct.

12              CHAIRMAN PITTS: Okay, let's see what  
13      questions there might be on page 1.

14              MS. SHIROMA: And basically the Panel wanted  
15      to make sure that we had fully articulated the benefits of  
16      the new phase II reformulated regulations on the trends of  
17      1,3-butadiene and then also to clarify the indoor analysis  
18      as far as, again, articulating contribution from  
19      environmental tobacco smoke.

20              And then we had one calculational correction  
21      we wanted to include in the Executive Summary, and that's  
22      the fourth bullet.

23              CHAIRMAN PITTS: I'm just waiting, I'd be  
24      interested to hear any input. While we're waiting maybe I  
25      could raise one question on this that it may be a question

1 of consistency, again, in units and also may go a little  
2 bit beyond that. We have here a statement that, it's the  
3 third paragraph down, "All of the 1,3-butadiene  
4 concentrations reported in the document are given in ppbv,  
5 parts per billion volume, followed by the microgram per  
6 cubic meter equivalent."

7 And that's fine, except there's some confusion  
8 in some of the reporting in terms of from the Part B part  
9 from the OEHHA group because we have it in units of parts  
10 per million instead of parts per billion. And I guess a  
11 factor of 10 to the third is not a heck of a lot in the  
12 congressional bank, but in a document like this it can get  
13 a bit confusing.

14 An example maybe of this, then if you go below  
15 this it says, "On page 7, the estimated number of  
16 1,3-butadiene has been raised from 3,936," which is maybe  
17 more significant figures than we'd want to admit, "to  
18 4,200. This change is the result of the recalculation of  
19 the conversion of the 1,3-butadiene's ppm best value to  
20 microgram per cubic meter."

21 And I don't see how you convert units and you  
22 get a difference in the number of deaths by just changing  
23 units. I think I know what you did; I think you got a new  
24 value from OEHHA is what I think happened.

25 MR. HUGHES: Right.

1           CHAIRMAN PITTS: But it doesn't reflect that  
2     the way this is said. So you ought to think about that.

3           MR. HUGHES: Okay, the change from the 3,936  
4     to the 4,200 did come from the revised best value. So all  
5     I'm saying is that the Executive Summary got changed, and  
6     that number was changed to reflect the best value that is  
7     in the document now.

8           CHAIRMAN PITTS: But now you see you have a  
9     value here, if you look at this it is in fact -- when you  
10    go to the comments here that are from, let me go back here.  
11    On Part B it says, "Changes to the Executive Summary," and  
12    Part B, and this really throws me, the third change to the  
13    Executive Summary: "On page 7," -- and by the way, I want  
14    to compliment OEHHA for giving the page and the paragraph  
15    and the line number. That kind of helps if we do that  
16    throughout because you're kind of scanning these things.

17                   But it says, "change '1.6 times 10 to the  
18    minus 4 per microgram per cubic meter' to read '0.37 per  
19    part per million (1.7 times 10 to the minus 4 per microgram  
20    per cubic meter)'."

21                   Now, I think if we stay in micrograms per  
22    cubic meter, the 1.6 to 1.7 is reflected in the 39  
23    something to 4,200. I think that's how you really got it.  
24    But, boy, I don't see how this 0.37 ppm ought to be in  
25    ppb's.

1 MS. SHIROMA: In parts per billion.

2 CHAIRMAN PITTS: We agreed on that.

3 MS. SHIROMA: Right, right.

4 MR. HUGHES: OEHHA probably could better  
5 handle this.

6 MS. SHIROMA: But your point is well taken.

7 CHAIRMAN PITTS: And maybe that's how they do  
8 it. But when you do it in the Executive Summary you want  
9 it consistent.

10 MS. SHIROMA: And our intention was in the  
11 third bullet on the Executive Summary was to assure that  
12 both Part B and Part A and the Executive Summary were all  
13 consistent.

14 CHAIRMAN PITTS: That's right.

15 MS. SHIROMA: And I apologize for our missing  
16 that.

17 CHAIRMAN PITTS: That's okay, it needs some  
18 interaction. But I think it is important to clarify that  
19 and keep it.

20 And also, along that line I think we had  
21 agreed one of the things that would be useful, when you  
22 start out the Executive Summary and Part A -- well, you see  
23 for example when you have this list of the compounds we've  
24 done to date, they're all in ppbv's.

25 MS. SHIROMA: Right.

1                   CHAIRMAN PITTS: Let me make a point about  
2 this. We have this list of compounds and numbers, we have  
3 those in the findings, we have included those in the  
4 findings. I would think that it would be important to  
5 include this in the Executive Summary in every one. This  
6 document, people who read the Executive Summary don't  
7 necessarily have the findings, and it's very helpful to see  
8 where a compound lies with the number in the summary versus  
9 other TACs that have been identified. So if we could do  
10 that, it's just easy enough to do.

11                   MS. SHIROMA: Right. We can certainly do  
12 that. And it would provide just that much more information  
13 to the public.

14                   CHAIRMAN PITTS: And let's do that in the  
15 future, let's put it in the Executive Summary. I think  
16 it's in Part A, it may be in the appendix somewhere. Where  
17 does this appear, this list, in this document?

18                   MS. SHIROMA: Right now it appears -- it would  
19 appear in your draft SRP findings and then in your  
20 finalized findings.

21                   CHAIRMAN PITTS: But it wouldn't be in the  
22 actual documents themselves?

23                   MS. SHIROMA: It would become part of the  
24 Executive Summary once the SRP findings are appended to the  
25 Executive Summary.



1                   CHAIRMAN PITTS: Okay, so they'll be there.

2                   Well, I think maybe though even before it would be helpful  
3                   to have them both places.

4                   MS. SHIROMA: Sure.

5                   CHAIRMAN PITTS: Because at least for me I  
6                   wasn't sure, when I see 1.6 times 10 to the minus 4 and  
7                   compare it to everything else, that's a pretty hot tamale,  
8                   it's hot. And I'd like to compare it to some others that I  
9                   have some familiarity with.

10                  MS. SHIROMA: It's definitely possible for us  
11                  to add that in future documents.

12                  CHAIRMAN PITTS: Yes, that would be fine, if  
13                  you would, yes. So we'll clarify that point there.

14                  One other thing. While we're at it why not,  
15                  it might be helpful somewhere in here you might want to put  
16                  the molecular weight. Remember, we were going to have an  
17                  asterisk or something and say, here is the molecular weight  
18                  of the compound, and then how to convert from micrograms  
19                  per cubic meter to ppb. I've got them here, and there's a  
20                  little equation to show how you can do it. It's just  
21                  helpful to people if they want to do it.

22                  MS. SHIROMA: Okay, all right, will do.

23                  CHAIRMAN PITTS: It's not a big deal, but the  
24                  molecular weight certainly would be nice to have because  
25                  you need that to make a conversion.

1                   We've had an interesting situation that may  
2                   affect the tax policy of the State of California.  
3                   Professor Byus has been telling people that we have 20  
4                   million people in the state and we've had a rapid increase  
5                   to 30 million again, and that's pretty speedy. Because in  
6                   your changes to summary it says, we're quoting 4,200 among  
7                   a population of 30 million, and I'm never sure whether we  
8                   use 20.3 or 30 or whatever that is.

9                   MS. SHIROMA: Okay, with the recent update to  
10                  the census we have been providing these numbers for a 30  
11                  million population.

12                 CHAIRMAN PITTS: Oh, okay.

13                 MS. SHIROMA: So we have extrapolated. The 20  
14                  million comes from the network. The 21 station network  
15                  represents approximately 20 million people.

16                 DR. BYUS: I know. But we're just being --  
17                  we're going to do it now on the total number in the state?

18                 MS. SHIROMA: Extrapolate to the total number  
19                  in the state, that's right.

20                 CHAIRMAN PITTS: That will be the policy.

21                 MS. SHIROMA: Right.

22                 CHAIRMAN PITTS: Good, okay.

23                 Are there any other points or questions?

24                 (No response)

25                 CHAIRMAN PITTS: Well, that's fine. I think

1       that takes care of that.

2               MS. SHIROMA: Okay, thank you. And then the  
3       Health folks will come up next.

4               CHAIRMAN PITTS: Fine.

5               DR. FRIEDMAN: Excuse me, are you talking  
6       about the whole document or just the Executive Summary and  
7       Part A?

8               CHAIRMAN PITTS: That's the Executive Summary  
9       and Part A. You want to be sure about the Executive  
10      Summary, if there are any other questions about that.

11              MS. SHIROMA: And no further questions on  
12      Part A?

13              (No response)

14              MS. SHIROMA: Okay.

15              CHAIRMAN PITTS: No? Fine.

16              Oh, by the way, some of the additions, some of  
17      the paragraphs that were added are great, they really look  
18      good. They came out very well and they are just what needs  
19      to be said. It's well done.

20              DR. FROINES: I just had one, when are the 25  
21      88 data going to be out, available?

22              MS. SHIROMA: The first phase of the program,  
23      the greater than 25 ton per year sources, plus those  
24      districts that have a more comprehensive inventory, our  
25      emissions inventory group is expecting that towards the end

1 of the calendar year there should be some summaries  
2 available. They are still going through the QAQC, that  
3 information. And then the next two phases will phase in  
4 from there, the 10 to 25 ton per year sources and then the  
5 less than 10 ton per year sources.

6 DR. FROINES: Has industry provided the risk  
7 assessments to the State at this point?

8 MS. SHIROMA: The way the program works is  
9 that the risk assessments have been done for quite a few of  
10 the first phase facilities. And the way the process works,  
11 it goes to the district first then gets submitted to the  
12 Office of Environmental Health Hazard Assessment.

13 So Melanie's group has had an opportunity to  
14 review a number of the risk assessments. They formulate  
15 their recommendations on those and they go back to the  
16 districts. I'm not certain that any district other than  
17 the Bay Area has actually finalized those risk assessments.  
18 But they have been submitted, they are going through the  
19 process, and the State has had a chance to review quite a  
20 few of those. And perhaps Melanie can elaborate on that if  
21 you like.

22 DR. MARTY: We've reviewed about 100 risk  
23 assessments, most of those from the Bay Area District.  
24 We're working on South Coast District and Ventura County  
25 District risk assessments as well as some from the smaller

1 areas in the north.

2 DR. FROINES: Then it goes back to whom?

3 DR. MARTY: Then we make comments to the  
4 district.

5 DR. FROINES: To the local areas.

6 DR. MARTY: Right.

7 DR. FROINES: Where does the public obtain,  
8 including this committee, obtain those documents? And  
9 when?

10 DR. MARTY: They are public dockets so that it  
11 is possible to go to the individual districts. And also we  
12 have had to allow access to environmental groups to come  
13 into OEHHA, into our files, and look at the documents. I'm  
14 not sure you'd want the total number or the whole  
15 document. We're expecting 730 from the 25 ton per year,  
16 and they range in size from 115 pages to 3 or 4 volumes.

17 MS. SHIROMA: At this point there isn't one  
18 specific repository for the risk assessments. But one of  
19 the things that we're looking at is whether or not the  
20 State can move towards having a repository for results of  
21 the risk assessment and then also to have access to the  
22 documentation. We aren't there yet. At this point it  
23 rests with each of the local air pollution control  
24 districts around the state, and there are 34. But we are  
25 looking at a longer term goal of having that repository for

1 the OEHHA.

2 DR. FROINES: I should say the point of the  
3 question is that there are things like refineries and other  
4 sources of butadiene that would inform this process.

5 MS. SHIROMA: Yes, and definitely during the  
6 control phase. Even if some of those risk assessments are  
7 still in process, the control staff could go in and start  
8 taking a look at that and try to fold that into their  
9 evaluation.

10 CHAIRMAN PITTS: Fine.

11 Would you introduce yourself for the court  
12 reporter.

13 DR. MARTY: Yes. My name is Melanie Marty,  
14 and I am with the Air Toxicology and Epidemiology Section,  
15 pinch-hitting for George Alexeeff.

16 Let's go back and look at butadiene. The  
17 members have already reviewed the document, and there was  
18 an SRP meeting on butadiene as you know, and Dr. Joe Brown,  
19 sitting to my left, gave the presentation. Members of the  
20 Panel had some questions which we have answered with the  
21 suggested changes that you have all received. In addition,  
22 we have talked to individual members of the Panel to see if  
23 our answers answered the question.

24 The proposed changes were sent to everybody,  
25 and hopefully everybody has had a chance to review them.

1     Our proposed range of risk then, just for a final cap on  
2     the discussion, is 9.8 times 10 to the minus 6 per part per  
3     billion to 8 times 10 to the minus 4 per part per billion.  
4     And that estimate, that range, represents from the rat data  
5     to the mouse I data all tumors. The best estimate at  
6     present is 3.7 times 10 to the minus 4 per part per  
7     billion, and that is from the mouse inhalation II study.

8             If members of the Panel have other items they  
9     wish to discuss regarding Section B or Part B, now is the  
10    time. We have Joe Brown will probably be able to answer  
11    most of the questions. And also to my right is David  
12    Holtzman who has also worked on the document.

13            CHAIRMAN PITTS: Thank you.

14            DR. WITSCHI: I have a question. I talked to  
15    George, and George said that IARC is probably in all  
16    likelihood going to endorse the upgrading of butadiene so  
17    to speak. What I was wondering, do we have any knowledge  
18    about their reasoning, why they changed their conclusions?

19            DR. MARTY: I think we probably have a copy of  
20    some of their reasoning. I don't have it with me.

21            DR. BROWN: What I saw was a very brief report  
22    on a draft report, but it didn't go into great detail on  
23    the reasoning.

24            DR. WITSCHI: So you wouldn't know what made  
25    them change their mind?

1 DR. BROWN: I imagine it's based on some of  
2 the newer epidemiology studies that are available that are  
3 discussed in our responses to your comments of the last  
4 time. But I don't have a copy of it with me.

5 DR. WITSCHI: Well, you have two more  
6 epidemiology in here, one is the Divine and the other one  
7 is the Matanoski. But the Matanoski, that's the same  
8 people which have been around for a long time.

9 DR. BROWN: Yes, yes.

10 DR. WITSCHI: I mean, so that's something --

11 DR. BROWN: We have the same situation with  
12 arsenic where there are multiple studies on the same  
13 population in Taiwan. So that's something that happens.

14 What we don't have, we don't have their final  
15 report. We've received indications that they are going to  
16 adopt this change, but until it's finalized and we actually  
17 get the final report.

18 DR. FRIEDMAN: That draft, wouldn't that give  
19 the reasons?

20 DR. MARTY: Yes, it does. But unfortunately  
21 they haven't used a whole lot of citation. It is from  
22 Dr. Veineo to Dr. John Rosenbaum in OEHHA. I could read  
23 this to you if that would help answer any questions.

24 Under the section where they discuss human  
25 carcinogenicity data:



1                   "One U.S. cohort study of workers who  
2                   manufactured 1,3-butadiene monomers showed a  
3                   significant excess risk for lymphosarcoma and  
4                   reticulosarcoma. Although there was no  
5                   overall excess risk for leukemia, there was a  
6                   suggested increase in risk in a sub-group of  
7                   workers with non-routine exposure to  
8                   1,3-butadiene.

9                   "In a U.S. study of workers employed in  
10                  two styrene-butadiene rubber plants, there was  
11                  a suggested increase of risk for leukemia with  
12                  exposure to 1,3-butadiene in one of the  
13                  plants. No increase in risk was seen for  
14                  cancers of the lymphatic and hematopoietic  
15                  system other than the leukemia.

16                 "In a study of styrene-butadiene rubber  
17                 workers in eight plants in the U.S.A. and  
18                 Canada, there was no overall increased risk  
19                 for leukemia. However, a sub-group of  
20                 production workers had a significantly  
21                 increased risk. There was no apparent  
22                 increased risk for other lymphatic system  
23                 cancers overall, although a significant risk  
24                 was seen for production workers.

25                 "In a case control study nested within

1           this cohort of styrene-butadiene rubber  
2           workers, a large excess of leukemia was found  
3           which was associated with exposure to  
4           1,3-butadiene and not to styrene. In a case  
5           control study in the rubber industry, a large  
6           excess of lymphatic and hematopoietic cancers,  
7           including lymphatic leukemia, was seen among  
8           workers employed in styrene-butadiene rubber  
9           production. One study therefore specifically  
10          related increased risks for leukemia to  
11          exposure to 1,3-butadiene and not to styrene.

12                 "In other studies, the increased risks  
13           for leukemia and other lymphatic cancers  
14           occurred among workers whose exposure had  
15           been in the manufacture of 1,3-butadiene or  
16           styrene-butadiene rubber."

17                 (Dr. Seiber arrived at the meeting.)

18                 DR. MARTY: It sounds like that they have  
19           reviewed studies that have already been reviewed, and it  
20           would be interesting to know if there was more follow up.

21                 DR. WITSCHI: But you have no explanation why  
22           they changed their mind?

23                 DR. MARTY: No, that's right.

24                 DR. FRIEDMAN: Well, if you keep reading they  
25           usually tell the reasons why they arrived at the present --

1       they don't tell you why they changed their mind but they  
2       tell you why they arrived at the present conclusion.

3               DR. MARTY: Yes, usually they do. It goes  
4       through the animal carcino data, other relevant data, then  
5       it jumps to evaluation. "There is limited evidence for the  
6       carcinogenicity in humans of 1,3-butadiene." And then,  
7       "Overall, 1,3-butadiene is probably carcinogenic to humans,  
8       Group 2-A."

9               DR. BROWN: There's no critical analysis, it  
10       just jumps to conclusion.

11              DR. WITSCHI: Well, wait a minute.

12              DR. FRIEDMAN: I'll bet you if you read --

13              DR. WITSCHI: 2-A, that's not an IARC  
14       classification. What document are you reading?

15              DR. BROWN: Limited evidence is what they say.

16              DR. MARTY: Yes.

17              DR. WITSCHI: Yes, but what you were just  
18       reading, it's a 2-A, that's not an IARC classification, is  
19       it?

20              CHAIRMAN PITTS: 2-A, and possible is 2-B,  
21       right?

22              DR. WITSCHI: Okay, then I was wrong.

23              CHAIRMAN PITTS: 2-A is probable and 2-B is  
24       possible; isn't that right?

25              DR. FRIEDMAN: If you read the previous one it

1       probably would not have included some of the more recent  
2       epidemiological studies that sort of pointed specifically  
3       at the butadiene.

4                   DR. WITSCHI:   Probably, yes.

5                   DR. FROINES:   I assume it's a nested case  
6       control study.

7                   DR. MARTY:    I'm wondering if one of the  
8       changes was that styrene was considered a confounder, and  
9       this one little paragraph here seems to indicate that they  
10      do not consider that as being relevant to the leukemia.

11                   CHAIRMAN PITTS:   Yes, Dr. Friedman.

12                   DR. FRIEDMAN:   I was pleased at the changes,  
13      and I appreciate the fact that you took into account my  
14      comment about Phil Cole's combination of data.   But I had  
15      one concern about a sentence that appears on page 2-D3.  
16      It's in the third paragraph.   "OEHHA staff do not  
17      ordinarily aggregate data from different epidemiologic  
18      studies and draw conclusions."   And the next sentence was  
19      what bothered me.   "Mixing studies that observed  
20      associations between disease and exposure with studies that  
21      did not observe such associations will inevitably dilute  
22      the observed associations."

23                   That's true, but it sounds like you're saying  
24      we only want to believe the positive associations, and  
25      something that dilutes it is wrong.   I think there are good

1 reasons for not combining the studies, and I'm sure you  
2 know them, questions of comparable methodology and how you  
3 weight the different studies and so on. But to me that is  
4 not a good reason for not mixing studies, the fact that you  
5 may dilute an association. Maybe the truth is the absence  
6 of association and you're diluting that truth by combining  
7 it with a positive association.

8 DR. BROWN: Well, that needs to be rephrased I  
9 think.

10 DR. MARTY: Okay.

11 DR. GLANTZ: Why not just delete the sentence?

12 DR. BROWN: Just delete it.

13 DR. FRIEDMAN: Well, you may want to give some  
14 reason.

15 DR. GLANTZ: That concerned me too.

16 DR. BROWN: Yes, it sounds biased.

17 DR. GLANTZ: I mean, are you saying that you  
18 ignore studies that aren't positive? I mean, that's what  
19 it seems to be saying.

20 DR. FRIEDMAN: Yes.

21 DR. GLANTZ: I mean, is that what you  
22 operationally do?

23 DR. FRIEDMAN: I'm sure they don't.

24 DR. MARTY: No.

25 DR. GLANTZ: Okay. Well, then you should

1 delete the sentence because it sounds like you did. I was  
2 a little surprised when I read that too.

3 DR. FRIEDMAN: But you may want to give the  
4 reasons why you don't. I mean, here's an authority who did  
5 combine data and who may have good reasons for not wanting  
6 to do that, and I think that's reasonable to put them  
7 there.

8 MR. HOLTZMAN: Well, as we said in our  
9 response to your comment, Dr. Cole really did not present  
10 any detailed calculations or reasons for combining the  
11 studies, and I think perhaps that sentence was put in there  
12 to try and get at his motivation for doing so. He was in  
13 this instance a paid consultant for an industry group.

14 DR. FROINES: Well, I think that the one point  
15 is that that comment sounds like policy rather than  
16 science, and I think you want to give scientific  
17 explanations and not policy explanation in that.

18 And the fact that he was paid by industry is  
19 sort of irrelevant it seems to me because he's a very fine  
20 epidemiologist and is well respected. And I think that  
21 comment doesn't serve any useful purpose.

22 MR. HOLTZMAN: Sure.

23 DR. FROINES: But I think that talking about  
24 the limitations of combining studies is a matter of  
25 science.

1 DR. MARTY: Okay, yes, that makes sense.

2 MR. HOLTZMAN: We can do that.

3 With all due respect, Dr. Froines, the issue  
4 of whether his testimony was scientific and peer reviewed  
5 was discussed here at the last meeting, I was just picking  
6 up on that.

7 DR. FRIEDMAN: I don't like the implication  
8 either that because someone is a paid consultant that that  
9 makes them automatically biased.

10 MR. HOLTZMAN: I apologize for that  
11 statement.

12 DR. MARTY: I agree too, I've been a paid  
13 consultant before.

14 Okay, Dr. Friedman, did you have any more  
15 comment?

16 DR. FRIEDMAN: No, I was just concerned with  
17 that one sentence.

18 DR. MARTY: Okay.

19 DR. FRIEDMAN: But, again, I appreciate all  
20 the work you did in responding to my previous comments.

21 DR. BECKER: I just wanted to ask, were there  
22 studies done about, it says limited indoor monitoring. In  
23 smoking environments were there actual studies done of  
24 1,3-butadiene? And we asked that question before because  
25 the risks are so much greater indoors than outdoors and by

1 many orders of magnitude. And then I lost somewhere in  
2 there what was happening with that. You said that there  
3 was some data for that that you knew about; is that  
4 correct?

5 DR. MARTY: I think I might turn that over to  
6 Genevieve.

7 Genevieve, did you all look at that?

8 MS. SHIROMA: Dr. Becker, are you asking about  
9 exposure studies?

10 DR. BECKER: Right.

11 DR. MARTY: Right.

12 MS. SHIROMA: Dr. Becker, are you referring to  
13 exposure studies --

14 DR. BECKER: Yes.

15 MS. SHIROMA: -- of 1,3-butadiene? Okay, my  
16 understanding, and Joan and Kelly can edify if necessary,  
17 is that there have not been specific studies to quantify  
18 the 1,3-butadiene fraction of ETS. We know that  
19 1,3-butadiene is a component of ETS, and there have been  
20 studies on ETS indoors. We weren't able to quantify that  
21 portion, unlike formaldehyde.

22 DR. BECKER: Well, that was exactly the point.  
23 On the tentative findings, No. 9, it said limited indoor  
24 monitoring, and it lists 10 to 60 micrograms.

25 MS. SHIROMA: And again, Kelly or Joan can



1       clarify if necessary, but my understanding is that it's a  
2       rough extrapolation.

3               DR. BECKER: So that's an estimate?

4               MS. SHIROMA: Yes, that's right.

5               DR. BECKER: I see. That was one of the  
6       questions that we asked about before because this is  
7       obviously the largest source. It seemed to me that that  
8       was where you'd want to make the monitoring measurements  
9       because that poses such a greater risk to people.

10              MS. SHIROMA: And our research division is  
11       following up on additional indoor studies.

12              And, Joan, do you know if they've included  
13       1,3-butadiene for those future studies?

14              MS. DENTON: Yes, they have.

15              MS. SHIROMA: Okay, the answer is yes.

16              DR. BECKER: It seems to me that in terms of  
17       what we communicate -- and the lead person, I guess it's  
18       Dr. Witschi, isn't it?

19              CHAIRMAN PITTS: For which? Part B or A?

20              DR. BECKER: For B.

21              I mean, it seems to me that they're going to  
22       ask you about that I would imagine because that's a much  
23       bigger source of potential exposure, indoor, so they may  
24       ask about that. And that's why I think that that No. 9,  
25       probably those are many orders of magnitude greater

1 exposure.

2 MS. SHIROMA: Right. And Dr. Glantz had  
3 brought up that issue at the last meeting, and we had a  
4 conference call with Peggy Jenkins, our indoor air expert,  
5 and Dr. Glantz. And realizing that it's important, it will  
6 be studied further because it does look to be important.  
7 But at this point we don't have that quantitative data.

8 DR. BECKER: Okay.

9 CHAIRMAN PITTS: While you're on this subject,  
10 there's one point here. On the Executive Summary there was  
11 a change made in line with this. "On page 4," this is the  
12 first page of what we have here submitted to us, Executive  
13 Summary, "in response to the question, 'What about indoor  
14 exposure to 1,3-butadiene?', the lead sentence has been  
15 changed from 'Indoor air may be the major route of  
16 exposure...' to 'Indoor air is almost certainly the major  
17 route of exposure to 1,3-butadiene for individuals exposed  
18 to a heavy smoking environment.'" That's a good statement.

19 DR. GLANTZ: My only concern there and also  
20 there's a couple places where they say heavy smoking  
21 environment, and I would like to see the word "heavy" taken  
22 out throughout because it's just an environment where the  
23 smoke is present. I mean, you don't have to be in a bingo  
24 hall in order to get high doses compared to outdoor doses.

25 MS. SHIROMA: Yes, I think we can go ahead and

1       remove that.

2                   DR. GLANTZ:  There's several places through  
3       the document.

4                   CHAIRMAN PITTS:  Could I continue with the  
5       point you've made here, and I think this is a point that we  
6       made at the last meeting also.  If we look at the risks,  
7       this table of unit risks, of all the compounds that we  
8       looked at it seems to head the list for gaseous, gas-phased  
9       species.  That's point one, okay.

10                  Two, I must have an old list, you will change  
11       the numbers?  Will these numbers be changed then, the  
12       risks?  Be sure we change them on this material that was  
13       handed to us.

14                  MS. SHIROMA:  Right.

15                  CHAIRMAN PITTS:  Okay, be sure of that.  And  
16       that will be changed in the Executive Summary; is that  
17       correct?

18                  MS. SHIROMA:  Yes.

19                  CHAIRMAN PITTS:  Okay.

20                  Now, we did raise the question if in fact we  
21       have something that has a risk -- and we'll put the error  
22       bars on the risk, that's fine -- that is that prevalent and  
23       that pervasive in the atmosphere, the Panel raised the  
24       question as to what steps are being taken to make more  
25       definitive measurements, quantitative definitive

1        measurements in the case of butadiene so that instead of  
2        being very general and they're qualitative, we can come up  
3        with an exposure assessment which will be somewhat  
4        equivalent to what has been done for formaldehyde which is  
5        another bad actor and in which some really first-class work  
6        has been done in establishing the concentrations one finds  
7        in mobile homes, typical homes, and so forth.

8                    My simple question is what is being done in  
9        this area of setting up a research program, carrying it  
10       out, and putting it on a high priority for a compound  
11       that's clearly -- if this is all correct would you agree  
12       that it belongs at the top of the list? Would the medical  
13       people agree from the OEHHA?

14                   MS. SHIROMA: Yes.

15                   CHAIRMAN PITTS: And what's being done to do  
16       this, and not just that will be supplementing --  
17       complementing actually, complementing the ETS work that  
18       we've been talking about?

19                   MS. SHIROMA: Dr. Pitts, two things. First of  
20       all as Joan confirmed for me, Peggy Jenkins' group in the  
21       indoor section of the research division is pursuing  
22       additional research studies to quantify the exposure  
23       indoor. I can't tell you what the dollar amount is of  
24       those studies, but I know that they are pursuing those, and  
25       we should be able to start seeing some analysis from that.

1       So additional data is being pursued.

2                       Now, in the meantime as I'm sure you're aware,  
3       we are always having to keep in mind as well that the Air  
4       Resources Board does not have indoor air authority in terms  
5       of risk management or control. 1807 does require us to  
6       address indoor air in our reports to you and then to the  
7       Board, so we are weighing very carefully the need to  
8       include that discussion, to get the data that's necessary  
9       for that to pursue it further if it looks to be an  
10      important actor.

11                      But we're also keeping in mind too in the  
12      grand scheme of prioritization of our resources and work,  
13      what else can we do? At this point we don't have that  
14      indoor air authority. But that's not to say that we aren't  
15      pursuing this, and in fact the research dollars are going  
16      to be placed towards getting that quantitative data for the  
17      butadiene.

18                      CHAIRMAN PITTS: Dr. Glantz.

19                      DR. GLANTZ: Yes. I had a long talk with  
20      Genevieve and Peggy Jenkins and some other people about  
21      just this issue because as you'll recall from the last  
22      meeting, I pressed them to come up with more specific risk  
23      numbers for indoor butadiene than the report has. I mean,  
24      it's got more than it did before, but it didn't go as far  
25      as I was asking last time.

1                   And basically the argument that was made to me  
2    which I think was a strong argument was that most of the  
3    butadiene almost certainly comes from ETS. And ETS is  
4    pretty well characterized, and in fact -- indoors -- and  
5    easier to characterize than its individual constituents,  
6    and that it's hard to just say just because you have a  
7    certain amount of ETS you have a certain amount of  
8    butadiene, or formaldehyde or polycyclic aromatic  
9    hydrocarbons or whatever because it depends a lot on the  
10   ageing and the specific physics of the situation.

11                   And they argued that they thought resources  
12    would be better put into looking at ETS as a mixture rather  
13    than trying to pull out the separate compounds. And since  
14    they are now moving ahead with looking at ETS, I actually  
15    think that they are right, that it's simpler and in the  
16    long run probably better to just deal with ETS as a whole  
17    rather than getting too concerned about the specific  
18    sub-constituents because the behavior of those constituents  
19    can be quite different, depending on the temperature and  
20    the air movement patterns and that.

21                   Now, that's not to say that this specific  
22    compound isn't worth looking at too. But I think that  
23    they're better off in an era of limited resources putting  
24    it into looking at ETS as a generic thing rather than  
25    trying to pull out how much butadiene there is from ETS.

1 They know there's a lot, they know that represents a major,  
2 if not the major route of exposure for most people, and the  
3 document now says that I think pretty clearly.

4 And so I was mollified on that point. And I  
5 think basically the direction they're moving is a  
6 reasonable one from a scientific point of view too.

7 MS. SHIROMA: Also, Dr. Pitts, in talking  
8 about the outdoor concentrations and risk, as you are aware  
9 the emissions are largely from motor vehicle exhaust and  
10 are some cold start emissions, and so the current control  
11 program is taking a hard look at that cold start accent.

12 CHAIRMAN PITTS: I understand that, and the  
13 reformulated fuels, you have a comment on reformulated  
14 gasoline.

15 I guess I have a question then of Dr. Glantz.  
16 How does one determine in a chemical sense what  
17 measurements are made to determine exposure from the Part A  
18 perspective to ETS? Do you measure particles, do you  
19 measure gases, do you measure total hydrocarbons, total  
20 organics, or what are the measurements made?

21 DR. GLANTZ: Yes.

22 CHAIRMAN PITTS: But you don't speciate them?  
23 You just say --

24 DR. GLANTZ: No, no, at least people haven't  
25 done that so far. Typically people will look at RSPs, at

1 total particulates, at nicotine because that's very  
2 specific to tobacco, and carbon monoxide, although that can  
3 come from a lot of different places. And we in some of the  
4 research we've been doing in chamber exposure studies have  
5 been looking at polycyclic aromatic hydrocarbons.

6 DR. FRIEDMAN: What are RSPs?

7 DR. GLANTZ: Respirable suspended  
8 particulates, small particles. And also total particulates  
9 which actually are turning out -- we've been looking at  
10 that too in these exposure chambers. And there's new  
11 technologies that make it easier to measure total  
12 particulates, and it turns out about a third of the total  
13 is RSPs, which the RSPs appear to be the important ones.

14 But these things all co-vary. And if you  
15 basically -- while it's hard to break out exactly what the  
16 different constituents are doing, they all tend when you  
17 stand back and look at it over orders of magnitude, they  
18 all co-vary together pretty well. So it doesn't matter too  
19 much what you measure as long as it's something that isn't  
20 confounded with a bunch of other variables.

21 So I don't think for example when they come to  
22 us with the ETS report, I'm not -- I mean, if they come  
23 back and say, here's how much formaldehyde we're detecting  
24 and how much butadiene and how much of this and how much of  
25 that, I mean, that would be okay. But I think what you



1 really want is some overall measure of exposure, and that's  
2 what most people have done.

3 Now, there have been some things looking at  
4 specific components, but there's three or 4,000 different  
5 things in tobacco smoke, so it's hard to look at all of  
6 them.

7 CHAIRMAN PITTS: Well, we generally agree on a  
8 number of issues, but I think I beg to -- well, I have a  
9 concern, I have a concern about effectiveness. I think if  
10 one can take a number, specific numbers versus the overall,  
11 and have a number of 10 to the minus 4 say, something like  
12 that or close to 10 to the minus 3 -- one of your numbers  
13 was almost 10 to the minus 3. Wasn't one of the new ones 9  
14 times 10 to the minus 4 or something that you gave us?

15 DR. MARTY: Yes.

16 CHAIRMAN PITTS: Isn't that right? I mean, it  
17 was close to 10 to the minus 3.

18 DR. MARTY: It was the upper end of the range.

19 CHAIRMAN PITTS: Yes, the upper end was what?

20 DR. MARTY: 8 times 10 to the minus 4.

21 CHAIRMAN PITTS: Okay, that's heavy duty. And  
22 I think frankly for your strategy for the idea of defending  
23 ETS, it seems to me that you might from what I've seen of  
24 PAHs and non-substituted and so on, you might have a very  
25 much stronger case actually if you turned the argument

1     around and said, we have the measurements of butadiene.  
2     Here is a number of 10 to the minus 3. You're in the ball  
3     game of the really heavy duty. And we can get numbers,  
4     butadiene can be measured. It's a little tricky, it's  
5     unsaturate, conjugate unsaturate and it's tricky. But I  
6     have the feeling that we can.

7             Now, also in terms of the ARB's mandates,  
8     formaldehyde, another constituent, has been measured  
9     indoor. The work that Peggy Jenkins and her crew has done  
10    I think is exemplary, I am just really impressed by that.  
11    On an international basis I have been sending out that  
12    material worldwide. People are really concerned. The  
13    numbers are there. And I think that on the one hand you  
14    may have a fight, we will have a big fight on ETS, and I  
15    want to continue to do it. But to pick out one actor like  
16    this that's this tough and really go for that would greatly  
17    strengthen the case in my opinion. So I just put that on  
18    from my perspective. But we can talk about it.

19            DR. BECKER: But I think the document more  
20    accurately reflects now, and also the document with the  
21    changes describing the epidemiology now, a more fair  
22    balance about exactly what it shows because it's more  
23    descriptive. I guess I share the same feeling that others  
24    have about if the IARC was going to change it we really  
25    ought to know why. Because they probably got the same data

1     that we have, and we had the same questions, so it's a  
2     little puzzling why they would do that. Because don't they  
3     have very rigorous rules and regulations about how they  
4     decide what goes into the 2-A or 2-B?

5             DR. FRIEDMAN: Well, no, I think if you would  
6     read the previous report, their previous conclusion, you  
7     probably would find that there weren't the same studies  
8     that were just cited now.

9             DR. BECKER: I see. Because they did upgrade,  
10    I notice that they have added these references, this 1990  
11    and so forth. They don't seem to add enough weight to  
12    change that from what I can see.

13            CHAIRMAN PITTS: Well, I agree, it's a great  
14    improvement, what's come into this. And I'm thinking more  
15    of the future, for the next round down the pike.

16            Okay, now let's continue.

17            DR. MARTY: Could I just make --

18            CHAIRMAN PITTS: Yes, by all means.

19            DR. MARTY: We could, for Dr. Becker and  
20    Dr. Friedman, follow up with IARC, talk to a few people  
21    there.

22            CHAIRMAN PITTS: Would you do that. Would you  
23    communicate and say that the Panel were concerned.

24            DR. MARTY: Sure.

25            DR. BECKER: I think because too that one of

1 the things that's a little confusing to me about the way it  
2 currently reads is it says we anticipate that IARC will be  
3 doing this. On the other hand if you said, "Because A, B,  
4 C, and D, IARC is doing this in light of that," then that  
5 would make it better.

6 DR. MARTY: I agree.

7 DR. BECKER: Because one of the things  
8 actually in going back over some of the documents in the  
9 past, this one looks like it's a little different in that  
10 there seem to be some things in motion. And I think it  
11 would be worthwhile saying, "Based upon communications with  
12 them that this has changed because..." I think that would  
13 help, become clearer.

14 DR. MARTY: Okay.

15 CHAIRMAN PITTS: Are there other comments?

16 (No response)

17 CHAIRMAN PITTS: Well, then I guess the next  
18 step is to consider the findings.

19 Now, I find that somewhere in this pile of  
20 material I must have some findings.

21 MS. SHIROMA: Yes. In fact, they're at the  
22 back of the -- we added one more copy.

23 CHAIRMAN PITTS: Did those findings reflect  
24 the latest numbers that we were just given for these unit  
25 risks?

1 MS. SHIROMA: Yes, they do. And I notice that  
2 we'll need to change to parts per billion.

3 CHAIRMAN PITTS: Great, okay.

4 MS. SHIROMA: It's the last four pages of the  
5 material.

6 CHAIRMAN PITTS: Dr. Becker, Item 1 was what  
7 you were pointing out, that's exactly what you were  
8 referring to, yes. And you're quite right, we should have  
9 some backup for the statement, "It is our understanding  
10 that.." Right?

11 DR. BECKER: Right. So I would just say,  
12 based upon whatever it was, IARC has made that change. It  
13 isn't clear to me from what you stated why they've done  
14 that. I also talked to George about that, and he wasn't  
15 sure either. He talked to me yesterday because I had that  
16 same question when he called.

17 MS. SHIROMA: So what we can do then is OEHHA  
18 can follow up with IARC to get to the bottom of the reasons  
19 as to the proposed change and incorporate that language,  
20 maybe talk to you, to Dr. Witschi, and Dr. Friedman,  
21 incorporate that into the findings for finalizing.

22 CHAIRMAN PITTS: That would be fine. That's  
23 good, excellent.

24 DR. BECKER: Well, I think if Dr. Witschi is  
25 going to present it, I'm interested in it, but I think it

1 would be important to make sure that he understands.

2 MS. SHIROMA: Absolutely, yes.

3 MS. DENTON: So, Dr. Pitts, we could say,  
4 "However, based on," then whatever the evidence is, "it is  
5 our understanding..."

6 MS. SHIROMA: And we'll run the language by  
7 Dr. Witschi.

8 CHAIRMAN PITTS: That's right, exactly, that's  
9 the way it should be.

10 MS. DENTON: Okay.

11 CHAIRMAN PITTS: On 4, I'm again back, would  
12 you change those units and keep everything consecutive?

13 MS. SHIROMA: My apologies, yes. Parts per  
14 billion, right.

15 CHAIRMAN PITTS: Because I have to sign this  
16 as Chair, and if I've forgotten that one I'm in trouble  
17 which might suggest that you might be.

18 MS. SHIROMA: Yes, I understand.

19 CHAIRMAN PITTS: That's the way it goes, you  
20 know. Okay, let's do that for sure.

21 MS. SHIROMA: Okay.

22 CHAIRMAN PITTS: And then we want to maybe  
23 agree too in the future that when it comes over you'll have  
24 them translated and we'll get together, and all in the same  
25 units, consistently.

1 MS. SHIROMA: A little extra coordination  
2 between ourselves for consistency, yes.

3 CHAIRMAN PITTS: No, I understand, because you  
4 may be using it in ppm, I understand completely how that  
5 could work.

6 DR. FRIEDMAN: Jim.

7 CHAIRMAN PITTS: Yes.

8 DR. FRIEDMAN: A question about point 4. I  
9 just wonder in the last line, "the actual risk may be  
10 significantly lower" whether there might be any confusion  
11 caused by the use of the word "significantly." You know,  
12 people often interpret that as statistically. I wonder if  
13 you might want to substitute a word like "substantially" or  
14 something like that.

15 DR. GLANTZ: Much.

16 DR. MARTY: We've used "much" in other  
17 documents.

18 MS. SHIROMA: If the Panel is comfortable with  
19 that, we'll change that word then.

20 CHAIRMAN PITTS: That's a good point.

21 MS. SHIROMA: "May be much lower."

22 CHAIRMAN PITTS: We're just taking a pause to  
23 go through this again, the findings for sure now.

24 DR. WITSCHI: I have a question for Finding 9,  
25 and I assume this refers to passive smokers. And do we

1 just forget about those poor souls who are still actively  
2 smoking?

3 MS. SHIROMA: This is environmental tobacco,  
4 so it's passive.

5 DR. GLANTZ: Yes, you might want to clarify  
6 that because I'm sure people, the active smokers are  
7 getting a very heavy dose too, much heavier. But that  
8 we've never considered.

9 DR. WITSCHI: They're beyond salvation anyhow,  
10 right?

11 DR. GLANTZ: Yes. Well, I don't know if  
12 that's true, but anyway.

13 MS. SHIROMA: We could modify No. 9 to say  
14 that a --

15 DR. GLANTZ: Why don't you say individuals  
16 exposed to environmental tobacco smoke. "Limited  
17 monitoring for 1,3-butadiene indicates that individuals  
18 exposed to indoor environmental tobacco smoke are almost  
19 certainly exposed to higher concentrations indoors than  
20 outdoors. The estimated dose for an individual spending  
21 three hours exposed to ETS is..."

22 MS. SHIROMA: Okay, duly noted.

23 DR. GLANTZ: You know, one thing I didn't do,  
24 how does that 10 to 60 micrograms compare to --

25 DR. WITSCHI: I had a question on that one on



1 the dose. You know, in all the other ones we refer to not  
2 strictly a dose but ambient concentrations of butadiene.  
3 And those 10 to 60 micrograms, wouldn't it be better to  
4 replace it with some atmosphere that they might be exposed  
5 to?

6 DR. BECKER: See, that was the question I  
7 asked earlier, that that's an extrapolated number that  
8 comes from what they know about ETS and its percentages,  
9 they don't know that. That was the whole basis for me  
10 raising that question because that number is so different  
11 when you talk about micrograms, and it sort of sits there,  
12 and then they're going to ask you, well, what's the meaning  
13 of that and how does that translate?

14 And that's why I was responding by saying,  
15 well, that's a much larger dose by comparison. I mean,  
16 when you're talking about the numbers that we're listing  
17 there of 10 to the minus 4 or 5 and you're talking about  
18 micrograms and whatnot, that's a lot of stuff.

19 DR. GLANTZ: If somebody spent three hours  
20 sitting outdoors breathing -- what was it?

21 CHAIRMAN PITTS: 0.37 ppb.

22 MS. SHIROMA: Or 0.82 micrograms per meter  
23 cubed.

24 DR. GLANTZ: Yes. Okay, if the same person  
25 was sitting outside just breathing for three hours, what

1       would their dose be?

2                   DR. WITSCHI: Well, that's a good question,  
3       but why not go the other way around and come up with some  
4       number what the butadiene concentration in a smoke-rich  
5       indoor environment might be.

6                   DR. GLANTZ: Well, that too. Yes, I --

7                   MS. SHIROMA: Perhaps --

8                   DR. GLANTZ: Go ahead.

9                   MS. SHIROMA: I'm sorry to interrupt. In  
10       thinking back to our discussions with Peggy Jenkins on  
11       this, I know that she was reluctant to go further because  
12       when you do put down an exposure rate it has a certain  
13       connotation that it's a quantitative connotation. I think  
14       she felt that the data really falls short of that, and  
15       that's why she suggests to you that you use this statement:  
16       individuals spending three hours is 10 to 60.

17                   DR. GLANTZ: Okay, okay. What we're saying  
18       though is that that needs to be compared to something in  
19       the same units.

20                   MS. SHIROMA: Oh, okay, I see.

21                   DR. GLANTZ: So if you took your outside  
22       exposure with average breathing rates for three hours and  
23       all that, what would that dose be? I mean, can you do that  
24       calculation?

25                   MS. SHIROMA: We can do that calculation. And

1       so what you're saying is we would say then, this compares  
2       with an individual spending three hours in an outdoor  
3       atmosphere, breathing in X amount of micrograms.

4               CHAIRMAN PITTS: Or the average, 0.37, which  
5       is the number you've taken in ppb.

6               DR. BECKER: If you multiply the numbers --  
7       it's going to be huge.

8               MS. SHIROMA: Here's the difference.

9               DR. MARTY: I get 0.0004 micrograms.

10              DR. BECKER: Right, that's what I'm saying.  
11       That's why I said the number, when I read that, of 60  
12       micrograms was an unbelievable dose for comparison  
13       purposes.

14              DR. GLANTZ: Well, then you should just maybe  
15       add that, to say this compares with 0.000000.

16              MS. SHIROMA: Okay.

17              DR. SEIBER: I don't think the number is that  
18       low. I just did it in my head, and it's more like one to  
19       two micrograms.

20              DR. MARTY: Oh, I'm looking at the wrong  
21       thing, never mind. I was multiplying by the wrong number.

22              MS. SHIROMA: We'll double check the  
23       calculation. But if the Panel wants that statement in  
24       there as a comparison, we'll put it in there.

25              CHAIRMAN PITTS: Absolutely.

1 DR. GLANTZ: Here is the sentence you could  
2 add. You could say, "The same individual spending three  
3 hours outdoors breathing the average ambient concentration  
4 of 1,3-butadiene would receive" --

5 CHAIRMAN PITTS: Of 0.36.

6 DR. GLANTZ: "of 0.36 ppb would receive an  
7 estimated dose of somewhere between 1 and 0.0000."

8 DR. FROINES: I think this is an extremely  
9 important issue because when you get around to nested case  
10 control studies and you're dealing with small populations,  
11 your controls might happen to be in houses where smokers  
12 are maybe getting a greater exposure, non-smokers may have  
13 a significantly greater exposure than people in the ambient  
14 environment. And so they will be classified as non-smokers  
15 for the purposes of epidemiology which will have a profound  
16 affect presumably on: they're not really non-smokers;  
17 they're really smokers who smoke a little less than  
18 smokers. And we don't take that into consideration when we  
19 do epidemiology for the most part.

20 DR. MARTY: That's right.

21 DR. FRIEDMAN: I'm sorry, I don't quite follow  
22 what you're saying. Are you talking about case control  
23 studies of the industrial pollutant or smoking or what?  
24 I'm just not clear on what you're talking about.

25 DR. FROINES: I'm simply saying that if you

1 have a significant exposure to environmental tobacco smoke  
2 and are classified as a non-smoker, the risk may be  
3 different than a person who doesn't have that environmental  
4 tobacco smoke exposure.

5 DR. FRIEDMAN: I can't argue with that.

6 DR. FROINES: But how we deal with controls  
7 with people who are non-smokers, we always assume that they  
8 have no exposure to tobacco smoke.

9 DR. FRIEDMAN: Right. I think more and more  
10 nowadays people are trying to measure passive exposure and  
11 throwing that into studies whenever possible.

12 DR. GLANTZ: Yes, I mean, there are a few  
13 studies where people have looked at what you call a true  
14 non-smoker like the Mormons in Utah or Seventh Day  
15 Adventists. And you end up, for example, when you use  
16 those people you find your risks of smoking-induced  
17 diseases among true smokers go way up because the passive  
18 smokers contaminate the control group.

19 I actually thought you were saying something a  
20 little different which is also important, and that is that  
21 when you're doing studies of these environmental toxins,  
22 you know, let's say you wanted to do an environmental study  
23 of 1,3-butadiene. If people were passive smokers, the  
24 secondhand smoker exposure can be swamping out the effects  
25 of any industrial exposures too or ambient exposures, so

1       that's another problem.

2                   DR. FROINES: Well, that's something that you  
3       would like to study.

4                   DR. GLANTZ: Oh, okay.

5                   MS. SHIROMA: Okay, we can add that sentence,  
6       and we'll double check the calculation.

7                   DR. SEIBER: I had a question, Jim, about  
8       No. 10. I can't remember the wording in the original  
9       letter that we looked at last meeting, but I think the word  
10      "rats" appeared in there, and I just wondered what happened  
11      to the rat information. We did agree to change and  
12      partition out the rats from the mice, but I see the rat  
13      information is not there, or else I've overlooked it.

14                  MS. DENTON: We're checking, we're trying to  
15      find the original finding.

16                  DR. BECKER: It says in finding 4 that it was  
17      related to rats and mice.

18                  DR. BYUS: Well, I have the original findings  
19      here. It looks like it said animals originally, now it  
20      says mice, which is probably more accurate.

21                  DR. SEIBER: It just seems to me a vague  
22      recollection that rats were much less sensitive than mice,  
23      that there were data with rats. Maybe somebody can correct  
24      me if I'm wrong.

25                  DR. MARTY: No, that's correct.

1 DR. SEIBER: So I guess my question then would  
2 be should that less sensitive animal model at least be  
3 cited to give completeness to the document?

4 DR. WITSCHI: I have also a question on 10.  
5 Do we want to keep the last two lines that butadiene is  
6 only one of two chemicals that cause tumors in the heart?  
7 Because really, we do not use this information, as a matter  
8 of fact we don't know how to use this information in the  
9 overall risk assessment, and if the sentence is there, all  
10 it might do is strike additional fear in the hearts.

11 I'm wondering whether this sentence is germane  
12 to the findings. I'm not disputing it, I'm just wondering  
13 whether it belongs in the findings.

14 DR. BECKER: What's the strength of it? I  
15 don't remember. How strong is that, do you remember the  
16 studies?

17 DR. WITSCHI: Oh, yes, it's very unusual. I  
18 mean, the statement is absolutely correct. And it's, well,  
19 what's the incidence of heart tumors, some 10, 15 percent I  
20 think.

21 DR. MARTY: It's high. Let me check.

22 DR. WITSCHI: It's quite high, it's quite  
23 remarkable.

24 DR. BYUS: I think it's a very unusual effect.

25 DR. WITSCHI: Yes, yes.

1 DR. BYUS: And I think it probably deserves to  
2 be in the findings, but this is at high doses --

3 DR. WITSCHI: See, but we don't use it.

4 DR. FRIEDMAN: You could add something,  
5 "Although not involved in the risk calculations, it is of  
6 interest to note that..."

7 DR. BYUS: Right.

8 DR. WITSCHI: Yes.

9 DR. FRIEDMAN: That would take some of the  
10 emotional aspect out of it.

11 I see what you're saying. You're saying, God,  
12 isn't that awful, it even caused tumors in the heart, and  
13 you want to get rid of that sort of emotional implication.  
14 Maybe a few words could do that.

15 MS. SHIROMA: Okay, so OEHHA can add some  
16 clarification on the context of that sentence.

17 CHAIRMAN PITTS: But leave it in.

18 MS. SHIROMA: Leave the information there, but  
19 clarify.

20 CHAIRMAN PITTS: That's fine.

21 On 13, now we're back to IARC again. On 13,  
22 to be consistent with what we said earlier, on 13 --

23 DR. MARTY: Pardon?

24 MS. SHIROMA: Number 13.

25 CHAIRMAN PITTS: I'm sorry.



1 DR. MARTY: I was just talking to Joe about  
2 the fact that the mouse tumors, that the hemangiosarcoma of  
3 the heart muscle is actually in the range of risk for the  
4 calculation.

5 CHAIRMAN PITTS: Okay.

6 And on 13, to be consistent with what we had  
7 up above, would you want to say that, again, add the  
8 qualification of IARC considerations making it now a  
9 probable. I mean, whatever qualifications you had earlier  
10 you would add instead of possible, because that just sort  
11 of says it bluntly and yet we've changed it up above in 1,  
12 okay?

13 MS. SHIROMA: Reflect the clarification on  
14 IARC in No. 13 as well?

15 DR. WITSCHI: Yes.

16 DR. GLANTZ: I think we could just say  
17 probable down here because we've already, I mean, we've  
18 already explained the No. 1 about IARC. We don't need to  
19 do it twice, just change the word.

20 DR. MARTY: Well, it's not finalized though,  
21 that's kind of tricky.

22 DR. GLANTZ: Well, how about saying, "Based on  
23 the evidence that it is an animal and probably probable."

24 DR. MARTY: And possibly a probable?

25 CHAIRMAN PITTS: And therefore it's probably

1 right.

2 MS. SHIROMA: Maybe a proposed probable by  
3 IARC, because that's basically what it is, it's a proposed  
4 probable.

5 DR. GLANTZ: Or you could say, any possible or  
6 probable human carcinogens.

7 CHAIRMAN PITTS: Yes, you could even put  
8 possible slash.

9 Just put a slash probable, possible/probable.

10 DR. GLANTZ: Or an "or."

11 CHAIRMAN PITTS: Then at least you're  
12 consistent.

13 MS. SHIROMA: Dr. Pitts, I just wanted to make  
14 sure that we addressed Dr. Seiber's comment about No. 10.

15 CHAIRMAN PITTS: About the rats?

16 MS. SHIROMA: Dr. Seiber, you mentioned about  
17 the rat information, and did we -- were you contemplating a  
18 separate finding or adding to this No. 10?

19 DR. SEIBER: Since I didn't have the last  
20 draft before me I can't remember what it said. But it  
21 occurred to me that rats were much less sensitive than  
22 mice, and I wondered if there should be a statement that  
23 it's also been identified as a carcinogen in rats but at a  
24 higher dose level, something just to make the database  
25 complete.

1                   CHAIRMAN PITTS: I think that's a good point,  
2 because I do remember we did have a considerable discussion  
3 about mice and men with Steinbeck and then rats.

4                   DR. SEIBER: I knew you'd remember that.

5                   CHAIRMAN PITTS: Yes, I remember that.

6                   Could we do that then, that's a good point, if  
7 there's no objection.

8                   MS. SHIROMA: Yes.

9                   DR. FROINES: Can I make one comment about  
10 13. It has to do with the notion of probable versus  
11 possible. My understanding of EPA, and I admit it's  
12 somewhat vague, is that if EPA labels something possible as  
13 opposed to probable that may impact their decision about  
14 doing risk assessments on the compound, that is that the  
15 naming of possible and probable has implications with  
16 respect to EPA's activities.

17                   When it comes to us, since by our naming it as  
18 a toxic air contaminant it is by definition, there is a  
19 risk assessment which is done and a regulatory process is  
20 going to follow, so that the issue of possible versus  
21 probable has no weight. Whereas with EPA it does have some  
22 weight, however they choose to deal with it.

23                   So it seems to me that we should be aware that  
24 the name that we choose to say should be what we choose to  
25 say because we already have done the risk assessment and it

1 is going to be regulated. So the term we choose should  
2 reflect our scientific understanding and the State's  
3 scientific understanding of the issue, it seems to me.

4 DR. GLANTZ: So which word are you proposing?

5 DR. FROINES: I'm not. I don't think it  
6 really matters very much. I guess it matters if people are  
7 going to sue you and you said possible versus probable.  
8 But I don't think anybody is going to do that, so I don't  
9 think it really makes a difference.

10 It seems to me if we think it's probable we  
11 should say that, if we think it's possible, or if we think  
12 it's probable/possible. I was just trying to raise the  
13 point that there is a difference between what we do and  
14 what EPA does, and so we shouldn't necessarily see  
15 ourselves bound by any of those terms.

16 CHAIRMAN PITTS: Well, one way to address this  
17 would be to ask OEHHA what would you people say is the  
18 term? We're evaluating your conclusions, and so let's hear  
19 your conclusion.

20 DR. MARTY: I'm probably sticking my foot in  
21 my mouth, but I think that most of the staff scientists  
22 that have looked at it would say it was probable. The only  
23 concern I have is we don't have an official State of  
24 California weight of evidence classification. And this  
25 could be confusing in that people will look at that and

1       then go back and look at EPA and IARC and say, that's not  
2       what it currently is, even though IARC is most probably  
3       going to change it to probable.

4               DR. GLANTZ: But as John said, we're making  
5       our own judgment. We've already said earlier on what IARC  
6       and EPA said.

7               MS. SHIROMA: I'm wondering if you can leave  
8       the language --

9               CHAIRMAN PITTS: Just leave it. Well, why  
10      don't we just declare it a toxic air contaminant as you  
11      have indicated.

12              Stan, we discussed probable/possible in the  
13      first item of these findings, and it clearly says with the  
14      modification that IARC is now going to --

15              DR. GLANTZ: Yes, why not just say, "Based on  
16      the available evidence indicating that 1,3-butadiene is an  
17      animal and human carcinogen..."

18              CHAIRMAN PITTS: Well, or just, "Based on  
19      available scientific evidence, we conclude that  
20      1,3-butadiene ..." I would rather say that.

21              DR. GLANTZ: That's even better.

22              CHAIRMAN PITTS: "Based on available  
23      scientific evidence, we conclude that 1,3-butadiene should  
24      be identified as a toxic contaminant."

25              DR. GLANTZ: Yes, that's better.

1 CHAIRMAN PITTS: That fits within the mission  
2 and the purview of our --

3 DR. GLANTZ: I move that we do that. I think  
4 that's a good idea.

5 MS. SHIROMA: "Based on available scientific  
6 evidence, we conclude that 1,3-butadiene should be  
7 identified as a toxic air contaminant."

8 DR. GLANTZ: Right.

9 CHAIRMAN PITTS: Inserting the bottom line.  
10 Is that agreed?

11 Are there other questions?

12 DR. BECKER: I make a motion that we accept  
13 the findings as modified.

14 DR. GLANTZ: Second.

15 CHAIRMAN PITTS: Any further discussion?

16 (No response)

17 CHAIRMAN PITTS: All those in favor?

18 (All ayes)

19 CHAIRMAN PITTS: Opposed?

20 (No response)

21 CHAIRMAN PITTS: It's unanimous.

22 DR. GLANTZ: Do we also need to make a motion  
23 that the report isn't seriously deficient?

24 MS. SHIROMA: Well, the statutes do say that  
25 you need to find that the report is not seriously

1       deficient, and then adopt your findings.

2               DR. GLANTZ: Okay, I move that we find that  
3       the report is not seriously deficient.

4               DR. FRIEDMAN: Second.

5               CHAIRMAN PITTS: Any further discussion on  
6       that point?

7               (No response)

8               CHAIRMAN PITTS: All those in favor say "aye."

9               (All ayes)

10              CHAIRMAN PITTS: Opposed?

11              (No response)

12              CHAIRMAN PITTS: And if anyone asks us why did  
13       we use the negative, not seriously deficient instead of  
14       saying, good show, good stuff, I think the response would  
15       be in the law it says that. That's why we're saying that.  
16       So if anyone ever asks you why do we use convoluted  
17       technologies if it's okay, it's the law. Right?

18              MS. SHIROMA: Right.

19              CHAIRMAN PITTS: And I think that, maybe I  
20       could speak for the Panel, I think we appreciate very much  
21       what all of you have done, put forth, the efforts of the  
22       staff on both sides, OEHHA and the ARB, the additional time  
23       and energies involved on your part to produce it, to come  
24       back for a second round, and to make these changes. We  
25       appreciate that because it improved the document, and good

1 show.

2 MS. SHIROMA: We thank you very much.

3 DR. FROINES: May I make just one comment  
4 about that. Since I presented formaldehyde last Thursday  
5 and it went through, the one thing I thought that the ARB  
6 actually liked and felt very positively disposed was the  
7 fact that we held two meetings on a compound, and that they  
8 felt that it added depth to the discussion and really said  
9 that -- I don't know if they said it explicitly, we'd have  
10 to look at the transcript -- but it was clear that they  
11 thought that that was a good thing for this Panel to have  
12 done.

13 Is that fair, Bill?

14 CHAIRMAN PITTS: That's an important comment,  
15 and I appreciate that in the context. I would also like,  
16 while you've made the comment, would you like to since you  
17 hit the perc, we have the formaldehyde, would you have any  
18 other comments about this meeting? You're looking well  
19 having survived that, and I think, you know, in terms of a  
20 risk assessment you've done very well on these.

21 You're up next, aren't you?

22 DR. FROINES: Yes, my comment was thank God  
23 somebody else is up next.

24 CHAIRMAN PITTS: That was my thought about it.  
25 Would you want to make any comments about the



1 formaldehyde discussions, or did any of it need to be --

2 DR. FROINES: No, I thought the discussion  
3 went very, very well. I thought George Alexeeff did a  
4 superb job presenting the Health -- I thought that the  
5 presentations on both Parts A and B were quite good. I  
6 thought that the industry was very responsible, had good  
7 comments and questions. I just thought it actually went  
8 very, very well. It seemed to me to go very smoothly.

9 CHAIRMAN PITTS: Well, that's good to hear.

10 MS. SHIROMA: Okay, and 1,3-butadiene we  
11 anticipate will be heard at the July Board hearing, and  
12 we'll be working with Dr. Witschi in preparation for that.

13 CHAIRMAN PITTS: What day in July is this  
14 going to be held, do you know?

15 MS. SHIROMA: It's the second Thursday of the  
16 month. I'm not sure which day that is.

17 MS. DENTON: July 9th.

18 DR. FROINES: I do think there are some issues  
19 about formaldehyde that will come up as we discuss, not so  
20 much perchloroethylene but the various letters. And I  
21 think by the way the letter that Tom Davis wrote on this  
22 issue is absolutely extraordinary. And I hope the Board  
23 has a copy of it.

24 CHAIRMAN PITTS: Yes, the letter, you all  
25 received copies of the letter, it was classic, absolutely

1 classic. We appreciate that.

2 DR. GLANTZ: Does the Panel, I mean, I felt  
3 the same way. Would it be useful for the Panel to sort of  
4 go on record as stating that Dr. Davis was speaking for the  
5 way people feel here?

6 CHAIRMAN PITTS: Well said and exactly.  
7 Would that be?

8 DR. BECKER: I think we should make a motion  
9 of that and support it.

10 CHAIRMAN PITTS: I would be delighted to hear  
11 such a motion.

12 DR. BECKER: So moved. I make a motion that  
13 we accept, endorse the letter and the spirit of the letter  
14 dated January 6, 1992.

15 DR. GLANTZ: And if I could add, that we  
16 direct the Chair to write a letter to the Board  
17 transmitting Dr. Davis's letter and pointing out that it  
18 represents the views not only of himself but the Panel.

19 DR. FRIEDMAN: Second.

20 CHAIRMAN PITTS: Any discussion?

21 (No response)

22 CHAIRMAN PITTS: All those in favor?

23 (All ayes)

24 CHAIRMAN PITTS: Opposed?

25 (No response)

1                   CHAIRMAN PITTS: Then it's carried. It shall  
2     be done.

3                   DR. FROINES: I think it's clear that the  
4     Board is going to be very interested in our participating  
5     in hearings that occur prior to the SRP receiving  
6     documents, that is workshops similar to that which have  
7     been held before which occurred during the document  
8     development phase, and not -- and I think I feel pretty  
9     strongly having sat through the perchloroethylene one that  
10    that's when the workshops should occur and should never  
11    happen when the document comes to us.

12                  DR. GLANTZ: But isn't that the way it is now?  
13    I mean, I went to the one on nickel.

14                  MS. SHIROMA: That's right.

15                  DR. GLANTZ: I mean, I agree, I went to the  
16    one on nickel and I found that very, very useful. But  
17    that's the new procedure, right? That's held before the  
18    document is written.

19                  MS. SHIROMA: That's right. And so for  
20    example, this summer we plan on holding a series of  
21    workshops on the compounds in progress now before they come  
22    before the SRP.

23                  CHAIRMAN PITTS: We had had a workshop on  
24    formaldehyde ahead of time too.

25                  MS. SHIROMA: Yes, we did.

1                   CHAIRMAN PITTS: I recall you and I were  
2 involved with that, yes.

3                   But that is, for the record, it is a  
4 commitment that we will have these before. As Professor  
5 Froines has indicated, it's really important to do that.

6                   MS. SHIROMA: An absolute commitment.

7                   CHAIRMAN PITTS: And then another, as long as  
8 we're on this subject and we're discussing this procedure,  
9 we also want to be sure as I recall that we receive the  
10 comments that have come in from the comments, Part Cs, and  
11 the revisions well ahead of our Panel meetings.

12                  MS. SHIROMA: Right, to give you, the Panel,  
13 the maximum amount of time to adjust the comments.

14                  CHAIRMAN PITTS: Yes, absolutely. It's really  
15 important. We have very, very busy and very involved  
16 people who are very concerned about the Panel, this is all  
17 the way around. They take it very seriously, I'm impressed  
18 with the Panel's performing their functions. So they want  
19 to do it seriously and well, and it requires then real  
20 time.

21                  We should err, if we're going to err, let's  
22 err by deferring the meeting date if we have to rather than  
23 receiving a package and in a very short period of time  
24 evaluate these.

25                  DR. FROINES: I think it's really important

1     though, going back to the workshop issue, the one thing I  
2     didn't say and I think everybody, I think everybody knows  
3     it, is that the industry people really would like members  
4     of the SRP to participate and be active in workshops. So I  
5     think that's part of what I'm saying, it's not just that  
6     they have them, but that we, some of us attend.

7             MS. SHIROMA: And that's also part of our new  
8     current system that we would arrange it so that it's a  
9     convenient time for both leads, Part A and Part B, to be  
10    able to attend these workshops as well. So, those of you  
11    who have compounds coming up, we'll be talking to you about  
12    dates and times for the workshops this summer.

13            DR. FROINES: Well, I say all this because --  
14    and I'm sitting here looking straight at Paul Cammer --  
15    because I would rather not have the Board tell us to go  
16    back and hold a workshop. It seems to me that that sets a  
17    bad precedent.

18            DR. GLANTZ: Well, but the thing was with  
19    perc, I think we all agreed that that was one that sort of  
20    fell through the bureaucrat cracks as far as the old  
21    procedures to the new procedures, and I really do think  
22    that was a special case.

23            MS. SHIROMA: Speaking of perchloroethylene,  
24    would you like the Office of Environmental Health to --

25            CHAIRMAN PITTS: I was just going -- we have a

1 question, I don't know how your flights are involved.  
2 Would you like to take a short break, it's noon, or would  
3 you like to go right ahead and handle the perc and then  
4 possibly we could adjourn at a reasonably early hour? It's  
5 up to you, the Panel.

6 DR. BECKER: Why don't we finish it off now.

7 CHAIRMAN PITTS: Why don't we go ahead.

8 Okay, well, let's go ahead with this and go to  
9 the next item, fine. Let's go to the discussion of the  
10 outcomes here of the workshop on perc.

11 And now, will you be prepared now to discuss  
12 this?

13 DR. MARTY: Yes. To my left is Dr. Lauren  
14 Zeiss who will do most of the discussing --

15 CHAIRMAN PITTS: Yes, good.

16 DR. MARTY: -- and answer most of whatever  
17 questions that you have. I do want to say that as a result  
18 of the February 4th workshop, there was some activity on  
19 OEHHA's part in reevaluating the cancer potency, and  
20 Dr. Zeiss will discuss what took place and the results.

21 CHAIRMAN PITTS: Fine.

22 Dr. Zeiss, do you have any notes there as to  
23 who attended and so forth?

24 DR. ZEISS: Yes, I do.

25 CHAIRMAN PITTS: And you're going to read

1       that?

2                   DR. ZEISS: I can go through that.

3                   CHAIRMAN PITTS: If you would just briefly go  
4       through that so we have a clear feeling, the Panel has a  
5       clear feeling of who attended and what was involved.  
6       Thanks very much.

7                   DR. ZEISS: All right.

8                   So, on February 4th there was a workshop held  
9       on perchloroethylene in Berkeley. And basically we  
10      assembled a panel of senior staff scientists of OEHHA and  
11      also with Dr. Froines, Dr. Dale Hattis of Clark University  
12      who is an expert in pharmacokinetic modeling, Professor  
13      Allan Smith of UC Berkely who is a professor of  
14      epidemiology. Dr. Becker also attended the workshop, and  
15      we also had extensive attendance by individuals from  
16      industry, the state, and other interested parties.

17                   The main focus, the main purpose of the  
18      workshop was to discuss what the best value should be for  
19      perc. Now, in the report there was presented a range of  
20      values. The focus of the workshop was to look at the best  
21      value, and key to looking at that was information on  
22      metabolism.

23                   We had presentations by DOW Chemical, ICI  
24      Chemical, the Halogenated Solvent Industry Alliance. And  
25      in their presentations, they looked at many of the key

1 issues that were addressed in the report. This included  
2 presentations on mechanism of action, cancer bioassay,  
3 strength of epidemiology data, and pharmacokinetics. But  
4 again, the focus of the workshop discussions was on the  
5 selection of the best value.

6 There was some new in vitro data presented at  
7 the workshop. Dr. Reitz of DOW Chemical presented some  
8 preliminary data developed after the report had been  
9 accepted I believe by the SRP. There was data on perc  
10 metabolism, in vitro data on perc metabolism by mice, rats,  
11 and human liver data.

12 Now, these data are qualitatively consistent  
13 with the mouse being a more rapid metabolizer of  
14 perchloroethylene than rats or humans. We asked Dr. Hattis  
15 who has several different pharmacokinetic models, including  
16 the model developed by DOW Chemical, we asked him to  
17 quantitatively look at this data. And he found that the in  
18 vitro data for humans was consistent with the model and  
19 with the data that we were using in that model. So the  
20 human metabolism data that was presented was consistent  
21 with that. However, the data for the mouse was not  
22 consistent with the pharmacokinetic model of DOW. So that  
23 was an important factor. So there was this inconsistency  
24 within the in vitro data.

25 The report presented interesting data;



1     however, it was wasn't peer reviewed, it was preliminary  
2     data, and I think the work group saw it as such, the  
3     workshop panel. So that there was a consensus I think I  
4     can say that the panel felt that the information was in  
5     general useful, but the degree of usefulness for actually  
6     looking quantitatively at what might be occurring and what  
7     a best value might be was extremely limited in that  
8     regard. So overall, we found that the in vitro data which  
9     has yet to be peer reviewed did not provide an adequate  
10    basis for the selection of a best value.

11           Now, there was also extensive discussion on  
12    the data in humans indicating metabolism, I'm talking about  
13    in vivo data, occupational exposure study and controlled  
14    exposure studies. The OEHHA document uses the  
15    pharmacokinetic data from a Japanese study to establish the  
16    best upper bound estimate of the fraction of  
17    perchloroethylene metabolized, and there was a lot of  
18    discussion over what studies should be used to select the  
19    fraction of perchloroethylene metabolized. Dr. Reitz of  
20    DOW argued that the Monster data should replace the Ikeda  
21    data for this purpose, and the panel discussed pros and  
22    cons of one data set over another.

23           Staff, after the workshop, OEHHA staff, looked  
24    at the consistency of the human data sets and whether or  
25    not all the data could be combined. And as part of this,

1     this involved the Monte Carlo simulations using the  
2     pharmacokinetic model, and this is basically the  
3     pharmacokinetic model of DOW. The results of this analysis  
4     is that at high doses, say of order of 50 ppm, the human  
5     data are fairly consistent and all indicate metabolism, the  
6     amount of perchloroethylene metabolized of order 1 to 12  
7     percent. So they hung together at high doses.

8             At lower doses there wasn't complete  
9     consistency across the different data sets, with some data  
10    sets indicating much greater metabolism, up to 35 percent.  
11    Each data set has its own problems, so there was no clear  
12    reason for choosing one data set over another. So  
13    consequently based on this analysis we didn't find a  
14    compelling reason to change our approach in calculating the  
15    best value.

16            However, we asked Dr. Hattis to look again,  
17    rerun his model and look again at the data set that we used  
18    to estimate the upper bound for the best value. He did  
19    this. He is using a slightly modified pharmacokinetic  
20    model from the one that he used a few years back, the one  
21    on which we're basing our original best value.

22            The result of this analysis was that instead  
23    of finding that 25 percent of inhaled perchloroethylene  
24    could be metabolized or is metabolized by humans, he found  
25    that 18 percent is metabolized. So this would result in a

1     slight change in our upper bound, our best upper bound  
2     estimate from 54 times 10 to the minus 6 per ppb to 40  
3     times 10 to the minus 6 per ppb. And so we recommend using  
4     this new value as the best value.

5             But we want to reiterate that we recognize the  
6     uncertainties in determining a potency value for  
7     perchloroethylene. So in the document we have presented a  
8     range of values, and we would encourage the Air Board to  
9     look at this range, and we would offer assistance in  
10    determining how one can or the information in this range  
11    and as further information becomes available, how to use  
12    this range in developing risk management options. So we  
13    would like to work with the Air Board to use this range to  
14    a greater extent. Thank you.

15            CHAIRMAN PITTS: Thank you.

16            Any other comments?

17            DR. GLANTZ: So am I to understand that from  
18    our point, I mean, there are certain things that the Board,  
19    the Air Resources Board has to worry about and has gained  
20    from this. But from our point of view as the SRP, it  
21    sounds like the bottom line is that we don't really need to  
22    reconsider the report that we've approved; is that true?

23            DR. ZEISS: Yes, except for the percent  
24    metabolism, the change in the percent from 25 to 18  
25    percent.

1 DR. GLANTZ: Okay, but that would be in the  
2 nature of a technical correction. It's not something that  
3 would cause us to reopen our proceedings on the report that  
4 we've already approved; is that true?

5 DR. FROINES: I think that's a fair statement.

6 DR. GLANTZ: Okay.

7 DR. FROINES: I think that there's subtlety in  
8 what she said though insofar as -- what is the metabolism  
9 range you're currently operating with?

10 DR. ZEISS: I believe around three to --

11 DR. FROINES: I thought it was five.

12 DR. ZEISS: Five to 74, it depends on how  
13 you're calculating percent metabolized, but of order of 3  
14 or 5 to 74.

15 DR. FROINES: I think that there is a distinct  
16 problem here. I basically agree with Lauren that the 18  
17 percent figure is an appropriate value.

18 DR. GLANTZ: Is or isn't?

19 DR. FROINES: It is. It is an appropriate  
20 value. But I just had one other comment to make about it.  
21 And that is that there are four data sets, the Ikeda data  
22 which gives you the upper bound which is the number that  
23 they're using; another Japanese study; a study by Monster  
24 which has a problem because it only has four -- there are a  
25 number of problems with it, one of which is there are only

1 four people in the study; and the Fernandez data. And the  
2 question is is which if any is correct?

3 And at some level I think it's fair to say  
4 that we don't really know. We really don't know. And some  
5 are better than others, but there are problems that can be  
6 raised about each of them perhaps. And so in a sense what  
7 we're doing is we're making a best guess. But at the  
8 current time, I think it's fair to say that we don't have  
9 the goal standard, if you will, for how much  
10 perchloroethylene is metabolized in humans, so that there  
11 is significant uncertainty in what is going on, and as far  
12 as I'm concerned that the decision by OEHHHA to basically  
13 stick with the value that they selected is entirely  
14 appropriate.

15 It's a very reasonable data set, and it wasn't  
16 shaken during the point of the discussion at the workshop.  
17 The people really did have differing points of view. Dick  
18 Reitz, who is an extremely fine scientist for DOW and one  
19 of the best in the United States when it comes to  
20 pharmacokinetic modeling, there's absolutely no question  
21 about his merit and scientific capability, really does  
22 prefer the Monster data. And others, including Hattis --

23 DR. BECKER: I thought it was two to three  
24 percent.

25 DR. FROINES: Well, something like that. But

1 I think that Hattis, who has looked at all of it and who is  
2 clearly the leading person in this area in the United  
3 States at this point, I think felt more comfortable using  
4 the Japanese data.

5 So I think that it's appropriate to use what  
6 we have. It's appropriate also to understand that there is  
7 a range, and finally that there is more experimental work  
8 that's required to ultimately resolve the question.

9 Is that fair?

10 DR. MARTY: I think that's very fair.

11 MS. SHIROMA: Could I just consult with Lauren  
12 and Melanie for a moment and we'll get right back to you  
13 folks with this discussion?

14 DR. MARTY: We think it's appropriate for us,  
15 OEHHA, to submit something written regarding the discussion  
16 that Lauren just gave, or the presentation and including  
17 the data that was presented at the February 4th meeting  
18 and then our reasoning for using the 18 percent.

19 DR. FROINES: I think that a brief  
20 clarification of what you think about the four data sets  
21 would be very valuable to give. So we don't try and redo  
22 the workshop and all the arguments right now, it seems to  
23 me it should be in writing so people can study it. Because  
24 it's very complicated and difficult, and it seems to me  
25 this is probably not -- we should have something to read

1       before we talk, if we could do that.

2               DR. BECKER: And there was also discussion  
3       about surface area corrections too in there.

4               MS. SHIROMA: Yes.

5               DR. BECKER: I would include that also because  
6       they were, to me it was very interesting to see what the  
7       data looked like at high dose levels and low dose levels.  
8       And it seemed to me that that needed to be a point, that  
9       there was contention on the part of people of what it was  
10      like at a high dose, what it was like at a low dose. So I  
11      would recommend that you write it out and deal with the  
12      surface area correction which they discussed as well as the  
13      percent metabolism which made sense.

14              And I, just as a person who, just as another  
15      person who was there as a member of the panel, I thought  
16      that was a very useful exercise, and I really encourage  
17      that because it made it a lot easier for me to understand  
18      exactly the data that was being presented and what the  
19      controversies were about, and then it was very valuable to  
20      see both sides present the information and have it done in  
21      an open forum. I found that to be very valuable and very  
22      rewarding. And then I think it would be appropriate as a  
23      model here to then have that written up and have us as a  
24      group come back and reach some formal conclusion about it.

25              DR. MARTY: I might add that we did tape it.

1 DR. FROINES: Yes, but I think Lauren can  
2 summarize it.

3 DR. ZEISS: You don't want to listen to  
4 several hours?

5 DR. FROINES: Towards the end of the day you  
6 got pretty much, people were arguing points of view.

7 I think it's very important to look at the  
8 issues around the model -- not around the models but around  
9 the metabolism, and be clear about issues of saturation at  
10 high dose and what have you, so that people feel some  
11 measure of confidence in what decisions they're being asked  
12 to make. And I think that one could argue that a range is  
13 a better way to go than a specific number. But to the  
14 degree that we feel -- for our purposes to basically agree  
15 upon a number, then it seems to me we're going to have to  
16 make a decision.

17 DR. SEIBER: Is the discussion here whether we  
18 need written minutes from the workshop, a summary of the  
19 workshop? Is that basically what we're discussing?

20 DR. FROINES: I don't know because I don't  
21 know the legal part. Because then the question comes is  
22 does what you write up then have to go out for comment?  
23 And I assume, again I'm looking to Paul who I think I know  
24 what his answer would be. But your judgment on that is --  
25 I don't know what the answer is to it.



1 DR. SEIBER: The alternative would simply be  
2 to have a written summary of what was presented orally  
3 here, that I could certainly support. But I'm a little  
4 concerned about going the minutes route without having that  
5 iteration of the participants making comments.

6 DR. FROINES: I don't think it should be  
7 minutes. Minutes would just confuse everybody, including  
8 the participants. You know, when you read the minutes,  
9 they're never as clear as what you thought was being said.

10 DR. GLANTZ: Well, then what are you saying we  
11 should do to bring this to closure? I mean, I agree with  
12 Dr. Seiber. I haven't heard anything that makes me think  
13 we want to reopen this as an issue before the Panel. So  
14 what can we do to bring it to closure, at least as far as  
15 we're concerned?

16 MS. SHIROMA: Well, our thought was that, as  
17 Melanie was describing, that basically they would draft an  
18 addendum to the Part B which would summarize the discussion  
19 at the workshop plus append the information that was  
20 provided at the workshop with a recommendation for your  
21 review and approval. And in the interim, we would go to  
22 our board, in fact on April 9th, and give them an oral  
23 status report of the workshop and the work in progress.

24 DR. GLANTZ: But as somebody said, does that  
25 have to go out to public comment? Because I mean, we have

1     this letter from this lawyer who clearly has a more  
2     pessimistic view of the quality of your decision than you  
3     did. I mean, I don't want to have to get into a whole big  
4     long discussion about this; we'll use up a lot of your  
5     resources and ours to no useful end.

6             DR. FROINES: I'll say one thing about what  
7     happened at the workshop. I think that Lauren and George  
8     have some of the most qualified scientists that I have ever  
9     seen on any issue, and I think this panel should feel very  
10    confident in the thoughtfulness and the scientific rigor of  
11    their deliberation.

12            DR. GLANTZ: But still, what should we do?  
13    How should we proceed to bring this to closure without  
14    making a lot of work for people?

15            MS. SHIROMA: Okay, we were just recollecting  
16    the direction from the Board. And to paraphrase, the  
17    direction was that they wanted the OEHHA to conduct a  
18    workshop with the various scientists present, that if based  
19    on that workshop the best value were to change, then to  
20    bring that back to the SRP for approval and then to give a  
21    status report to the Board.

22            So in that context of what the Board directed  
23    all of us to do, I guess our thought at this point is that  
24    the OEHHA will go ahead and write up a short summary as an  
25    addendum, present that to you, and then finalize the work.

1 DR. GLANTZ: Will that go out to public  
2 comment or that will just be a report?

3 MS. SHIROMA: We hadn't anticipated another  
4 public comment period.

5 DR. GLANTZ: Okay. So basically before the  
6 next meeting we'll get a short addendum to Part B that we  
7 would then say, yes, this is okay with us to add this to  
8 Part B; is that what you're saying? Or we would just take  
9 note of it, or what would we, after we get it what would we  
10 do with it?

11 MS. SHIROMA: We basically need to have you  
12 focus on the analysis that was conducted by OEHHA and  
13 assure that you concur with that analysis and the  
14 conclusions reached.

15 DR. GLANTZ: So, would the formal action then  
16 be that you will send a letter to us or a report to us,  
17 more as an information item, and then we would read it and  
18 maybe say we have taken note of this and have no problems  
19 with it rather than any sort of formal "not seriously  
20 deficient" kind of stuff? Is that what you're saying?

21 MS. SHIROMA: That's right, that's right.

22 DR. GLANTZ: Okay. So this would come to us  
23 in the nature of an information item rather than an action  
24 item? I mean, things do come to us for sort of our note  
25 and discussion from time to time. Is that how you're

1     saying this is going to be handled?

2                 MS. SHIROMA: Because the best value is  
3     changing, we will need your concurrence on that, if you  
4     agree. So it's not just an informational item.

5                 CHAIRMAN PITTS: You raised an interesting  
6     point, the numbers will change. We have had the workshop  
7     in detail, and it may well be -- I'm a little uneasy in not  
8     sending it out to public comment. I think it should go to  
9     the public. It may slow by a month or two or three,  
10    whatever the process is, but it should go public, and that  
11    the Panel -- this is just my personal opinion, I want to  
12    hear what the Panel, however you want to go. My feeling is  
13    though it should go out for public comment and then should  
14    be, the comments and the public comments, that should come  
15    back to the Panel and that the Panel formally should make  
16    some decision on how it will be handled.

17                MS. SHIROMA: If that's the direction of the  
18    Panel, we --

19                CHAIRMAN PITTS: Well, I'm just sort of  
20    tossing that out. I'd like to hear the Panel's opinion.  
21    That's just, not speaking as the Chair, speaking as a Panel  
22    Member. And there's a factor in here too that was  
23    extremely important and brought up in this whole question,  
24    that is these numbers really are significant in terms of  
25    the management sides. I don't know where these two numbers

1     lie in terms of the so-called, you remember the bright  
2     line? I always thought that was from Fordham, that was the  
3     backfield at Fordham about 40 years -- never mind, that's  
4     another football story.

5             But the bright line, you see, maybe it's  
6     Washington these days, but there's a line, and if the  
7     number is above the line certain things take place, and if  
8     it's below the line certain things don't take place. And  
9     it's an actual break, I mean, it's a mathematical  
10    discontinuity at that line basically, you don't have a  
11    trend. And this is important enough that -- and this is a  
12    very serious issue. If it's below it, it's okay; if it's  
13    above it, bingo.

14            So the whole matter should be treated with a  
15    great deal of thought and procedurally in such a way, sort  
16    of slow and steady wins the race in the sense that it be  
17    done in an appropriate fashion, plenty of comment, so when  
18    the final decision is made -- whatever it will be from the  
19    Panel, and we won't judge it now -- it will be a decision  
20    based on input from all, as we had in the past. It will be  
21    just as though we saw it in the beginning and had raw  
22    information.

23            Would that be okay? How does the Panel feel  
24    about that? Is there any problem with that?

25            DR. SEIBER: I see your point, Jim. And I

1     tend to agree, the more public review of what we do the  
2     better. But in this case it seems to me OEHHA was giving  
3     us a recommendation, not a summary of the entire workshop  
4     but their recommendation based on what they heard at the  
5     workshop, and we're simply asked to concur or not concur  
6     with their recommendation.

7                 Now, that's not to say that they quoted  
8     accurately what somebody said at the workshop, that's a  
9     question of minutes and proceedings from a workshop. So I  
10    guess even though I tend to always go on the side of more  
11    slow and public comment, the more, the better, in this case  
12    it just didn't seem like it was necessary because we're  
13    concurring with their opinion, not with the consensus of  
14    all the participants in the workshop. I don't know, maybe  
15    I'm missing a fine line here.

16                CHAIRMAN PITTS: How do you feel?

17                DR. FROINES: If we want to take that course,  
18    it's perfectly reasonable.

19                DR. MARTY: I think it is worth noting that  
20    none of the arguments have changed substantially, if at  
21    all.

22                DR. GLANTZ: Yes, see, my concern in this is  
23    it sounds like basically what they've done is made a  
24    technical correction. I haven't heard anything which is  
25    qualitatively different. It's that a couple of numbers

1       were changed based on better information.

2               DR. FROINES: We went from oral to inhalation,  
3       which is the preferred.

4               DR. ZEISS: There was also a slight additional  
5       thing in the Hattis model.

6               DR. GLANTZ: Well, I would suggest the  
7       following, why don't we do this. They can let them write  
8       the report and then let -- why don't we leave it to the  
9       staff and the ARB's lawyers whether to just send it back to  
10      us for us to take note of it or whether there's a need for  
11      some more. Because this thing has been very controversial,  
12      and it was all, again, basically a sort of accident of this  
13      transition to the new process. And if the ARB attorneys  
14      think it would be worth having this go out, you know, it's  
15      not going to be a long document so hopefully it will not  
16      precipitate a thousand pages of comments. And then it can  
17      come back to us at the time which is deemed appropriate.

18              DR. FROINES: I just want to say one thing.  
19      The person who made the suggestion about the written  
20      comments was Genevieve, and it seems to me that we as a  
21      panel can decide that we have heard, had sufficient  
22      discussion, following on Jim's point, and say we don't need  
23      written comments and we are prepared to go with that  
24      recommendation and not proceed further. So there are  
25      really two choices for us as a panel.

1 DR. GLANTZ: Well, I'm satisfied with just  
2 saying that this sounds reasonable to me and leaving it at  
3 that, if that's something the staff is comfortable with.

4 CHAIRMAN PITTS: Well, I think I have the  
5 feeling myself, it's sort of a feeling that, it's almost in  
6 fairness and in having gone to the major effort of holding  
7 a conference and having the distinguished scientists speak  
8 from both sides that, I'm not sure that what is lost by not  
9 going out to public comment and going out in hearing again,  
10 this is a proposal. Because after all, it's a major issue.  
11 And if it's a matter of a month, I mean, we'll read it, we  
12 should have the material, we should be able to examine it,  
13 and I think it's important to maintain confidence that we  
14 have gone through the process.

15 Let's put it another way, we've gone through  
16 90 percent or 95 percent. It would be a shame not to go  
17 the extra route and put it out to the public, comment on  
18 it. And then we can come back, and it may very well be  
19 that we will say exactly what you said, that this looks  
20 perfectly good, we agree. But there's a chance it may not.  
21 And for the record it would seem that it might be useful to  
22 go ahead and put it out.

23 But I'm prepared to take the vote of whatever  
24 the Panel, however you'd like to play this.

25 DR. FRIEDMAN: What sort of report were you



1       envisioning? Just a couple pages, not a big --

2               CHAIRMAN PITTS: Oh, no, I'm not expecting  
3       another report. We may get one back in public comment,  
4       but, no, it would be basically a report of what you've told  
5       us with whatever backup material you'd like to attach to it  
6       that may back up the statements of two pages, and then to  
7       the degree that the experts in our panel can go over this  
8       and say it looks fine, we'll read the public comments again  
9       on this several pages and then prepare to act on them.

10              DR. SEIBER: How about an alternative, Jim,  
11       where they prepare the written comments, we take a look at  
12       it and then decide after we see it whether it needs to go  
13       out for public comment. After all, if it's going to take a  
14       month it sounds like we might be here at another meeting,  
15       our next meeting with that document and the opportunity to  
16       discuss it then.

17              CHAIRMAN PITTS: Well, I think that maybe what  
18       I'm reflecting is actually having met some months ago with  
19       the Chief of Staff of the EPA, Brian Runkel, and with  
20       representatives of the industry and the OEHHA, and my sense  
21       of this was that it was really a matter of concern and  
22       importance to the industry and I think justifiably so  
23       within the frameworks of the procedure. This is why the  
24       workshop afterwards was a problem; that won't happen again.

25              But that there was a feeling that we did have

1 a chance to look at the last final value -- that is the  
2 public to respond to the last final value that in fact  
3 would be evaluated or voted on or approved by the Panel.  
4 So there is a great deal of interest in this, and it does  
5 in a sense, does maintain a tradition which I hope we will  
6 maintain of being sure that we do get, within the framework  
7 of our operation, the public comment of the type that this  
8 would represent. So it's on that basis.

9 And if it's a month, I don't really see -- or  
10 whatever the time would be. And there should be adequate  
11 time I might add for public comment too. If this is to be  
12 done it should be done as though we've actually made a  
13 major change in the document. It may not be, but it should  
14 be in that context.

15 DR. BYUS: I agree. I certainly would like to  
16 see the written summary, I think that would be very  
17 educational for me.

18 DR. WITSCHI: And the comments.

19 DR. BYUS: And the comments. But the issues  
20 were complex scientific issues, and I'd like to see -- I'm  
21 sure you did a good job, but I would like to see your  
22 analysis.

23 CHAIRMAN PITTS: Yes, this is not a criticism.

24 DR. BYUS: I mean, if you're going to do it,  
25 you might as well send it out for comment for another

1       however long it takes to make sure there's no problems. If  
2       it takes another month, it takes another month.

3                   MS. SHIROMA: Okay. Just so that we  
4       definitely understand, in terms of the overall perspective  
5       here that in listening to Lauren Zeiss's presentation to  
6       you, at this point her arguments and OEHHA's arguments  
7       sound reasonable as far as a change in the best value. In  
8       the meantime in terms of process, you basically would like  
9       a short written summary with a discussion of the reasons  
10      why for the small change in the best value and regarding  
11      whether or not there was any new evidence provided with a,  
12      perhaps a simultaneous SRP review and public comment with  
13      enough time for receiving those comments and having time to  
14      look at them and for us to be able to discuss them with  
15      you.

16                   CHAIRMAN PITTS: That's correct.

17                   MS. SHIROMA: Okay.

18                   DR. GLANTZ: If I could just, if we're going  
19      to do that, probably what we should do when we do this is  
20      we would slightly amend our findings to change this number.  
21      That would be the formal action we would take I guess. Is  
22      that true?

23                   CHAIRMAN PITTS: That's a good point. That's  
24      a very good point.

25                   DR. GLANTZ: So the thing that would come back

1 to us on the agenda would be an amendment to our previous  
2 findings based on the results of this workshop. Is that a  
3 true statement?

4 MS. SHIROMA: Yes, that's basically the  
5 upshot.

6 DR. GLANTZ: So why don't you do the  
7 following. In the report that you submit to us it would be  
8 a recommendation from you that the findings be amended  
9 based on the information from the workshop and then a  
10 justification for those changes. And then that could be  
11 sent out, that would hopefully be not a terribly long  
12 document. That could then be made available to the public  
13 and then come back to us, and we could simply vote to amend  
14 our findings. And that way it's nice and clean.

15 It that okay procedurally?

16 CHAIRMAN PITTS: Is that agreeable to the  
17 Panel Members?

18 Fine, then we'll go ahead.

19 DR. FROINES: When would we take it up, April  
20 or May?

21 CHAIRMAN PITTS: You've raised an interesting  
22 question because as I understand it from talking to Bill  
23 Lockett, the meeting might be several months away, the next  
24 meeting, because --

25 DR. BYUS: April 14.

1                   CHAIRMAN PITTS: Well, it's listed, that's  
2                   what I have in my little black book, but I understand we  
3                   may not have a -- we do not have another compound coming up  
4                   at that meeting.

5                   MS. SHIROMA: That's right.

6                   CHAIRMAN PITTS: So this ought to be put then  
7                   in the context of the timing.

8                   Bill, would you like to comment on this?

9                   MR. LOCKETT: Mr. Chairman and the Panel, the  
10                  next compounds coming up are acetaldehyde and the BAP lead  
11                  and the diesel exhaust. But those are heading for  
12                  workshops this summer, and so when those will come back to  
13                  you will be in the fall. So the agenda items for the Panel  
14                  are not clear at this point as to when there would need to  
15                  be a next meeting.

16                  Now, OEHHA is working on the cancer policy,  
17                  and the Panel has indicated an interest in the cancer  
18                  policy. That's another possibility.

19                  MS. SHIROMA: Overall, I'm thinking in terms  
20                  of timing to provide these folks sufficient time to write  
21                  the document, have a public comment period of perhaps 30  
22                  days and simultaneous review by all of you and time to  
23                  receive comments and so forth, that perhaps May would be  
24                  the best.

25                  CHAIRMAN PITTS: I think I have the 21st of

1 May. Do the rest of us have that down as a potential day?

2 DR. BECKER: Thursday.

3 CHAIRMAN PITTS: Thursday the 21st. Would  
4 that be reasonable time also then to send an agenda item?

5 DR. ZEISS: Sure.

6 CHAIRMAN PITTS: To bring this up as an agenda  
7 item, the perc, the cancer policy and other items that may  
8 be relevant.

9 MS. SHIROMA: And a staff report on the cancer  
10 guideline work that Dr. Zeiss is heading up, is that what  
11 you were saying?

12 CHAIRMAN PITTS: All we were saying, this  
13 would be one item then, a reexamination of the perc. Two,  
14 whatever. I'd like to hear what you propose would be on  
15 the agenda, that's what I'd like to hear. What do you  
16 propose to have on that agenda in addition to the perc?

17 DR. BECKER: What happened to the pesticides?  
18 We haven't heard about the pesticides.

19 MR. LOCKETT: The Department of Pesticide  
20 Regulation is apparently reexamining their 1807 program, so  
21 it might be timely to do that as well.

22 DR. BECKER: Why don't we invite them on the  
23 21st as well.

24 CHAIRMAN PITTS: That would be very useful.

25 DR. GLANTZ: What a waste of time.

1                   CHAIRMAN PITTS: Now, just a minute, in the  
2                   invitation I would formally like to ask what happened to,  
3                   was it methyl parathion that was next on the list?  
4                   Remember, we raised that question some time ago. Let's  
5                   raise the question again when the invitation goes out,  
6                   would they specifically discuss the compound, their list of  
7                   compounds, methyl parathion, which was under discussion two  
8                   years, I think it's almost two years now.

9                   DR. GLANTZ: Well, I actually now that you  
10                  bring it up have an alternative suggestion, and that is  
11                  that -- I think the pesticide component of AB 1807 is a  
12                  joke. I've been on this panel a long time, and we've seen  
13                  one, that they never acted on. And I would like to suggest  
14                  that the Panel send a letter to the appropriate people,  
15                  including Sally Tanner, the author of this legislation,  
16                  simply saying that the Panel has been in existence for  
17                  however many years it's been and there has not yet been a  
18                  single pesticide process through to conclusion and suggest  
19                  to Assemblywoman Tanner that perhaps they would like to  
20                  simply repeal the pesticidal portion of AB 1807 or do  
21                  something because the legislature should not think that  
22                  anything is happening. It's a joke.

23                  And I think, frankly, having had several  
24                  meetings where the pesticide people came before us and  
25                  assured us that pesticides never drift and that pesticides

1     are good for you and things like that, I think bringing  
2     them up here is a waste of the plane ticket. I mean, I'd  
3     rather see -- as a taxpayer I think it's waste of time to  
4     even bring them here. I think we could much more  
5     productively simply fairly loudly point out to the people  
6     in the administration and to people in the state  
7     legislature that that aspect of this law is simply being  
8     ignored.

9             DR. FROINES: I think we ought to have Stan  
10     Glantz go up with the ARB and discuss this issue.

11            DR. GLANTZ: Well, the problem, the ARB isn't  
12     the problem.

13            DR. FROINES: He would love it.

14            DR. GLANTZ: I mean, I'd be happy to do it,  
15     but the ARB doesn't seem to be the problem.

16            DR. FROINES: I just have an informational  
17     question. Is the pesticide program, is it now part of Cal  
18     EPA or is it still part of the Department of Food and Ag?

19            MR. LOCKETT: Right, thanks for the question.

20            CHAIRMAN PITTS: Did he set you up?

21            MR. LOCKETT: Yes, very nicely.

22            DR. GLANTZ: You're supposed to say, I'm glad  
23     you asked the question.

24            MR. LOCKETT: Right, I'm glad you asked that,  
25     Professor Froines. The Cal EPA reorganization which was



1 approved by the legislature took from the California  
2 Department of Food and Agriculture and created a Department  
3 of Pesticide Regulation which now resides within Cal EPA.  
4 An appointment has been made, there is a new director. My  
5 suggestion is that DPR be invited to come and make a  
6 presentation about their 1807 program before we go forth  
7 beyond that.

8 CHAIRMAN PITTS: I think that's fair enough.

9 DR. GLANTZ: Uch.

10 CHAIRMAN PITTS: Well, it is fair enough.

11 Then is then and now is now. But I would say though --

12 MR. LOCKETT: Give the new director a chance.

13 DR. GLANTZ: Grrr.

14 CHAIRMAN PITTS: Well, this is an opportunity  
15 to also say at this time in this letter of invitation that  
16 Stan's right, that we spent a great deal of time, the Panel  
17 did, on ethyl parathion. I'll never forget your comments  
18 about babies not being able to metabolize that up to six  
19 months.

20 DR. BECKER: Or was there data.

21 CHAIRMAN PITTS: Yes, was there any  
22 information on this. And a lot of effort went into that  
23 document. It went through the Panel here and then  
24 disappeared.

25 So why don't we just get the history of that.

1     Politely just say -- and that's a good reason -- here it  
2     is, this has been done, how do you see the possibilities or  
3     what actions do you see might be taken? And then the next  
4     one was to be methyl parathion, because I know we talked  
5     about that. That's on our list, and then there's a list of  
6     others. Ask them questions in the invitation so we can  
7     direct in part to get answers.

8                     After that, Stan, after that, then we'll see  
9     how --

10                    DR. GLANTZ: We've been doing this for years.

11                    CHAIRMAN PITTS: Well --

12                    DR. GLANTZ: I've gone and met with these  
13     people, and this is all deja vu all over again.

14                    CHAIRMAN PITTS: Well, Yogi, I'll tell you.

15                    DR. GLANTZ: But it's just a waste of the  
16     taxpayers' money. I think that one thing we should say in  
17     this letter is that the Panel is troubled that the contrast  
18     between the ARB and the pesticide portion of AB 1807 is  
19     quite dramatic, that there have been however many, 20 or so  
20     compounds processed by the Air Resources Board, that there  
21     has not yet been a single recommendation of this Panel  
22     which has been ignored by the Air Resources Board. And of  
23     the one pesticide that finally tortuously made it through  
24     the process, it was then simply ignored. And this, you  
25     know, it's a charade.

1                   CHAIRMAN PITTS: Well, other than that last  
2     statement --

3                   DR. GLANTZ: Other than that I think the  
4     process is working.

5                   CHAIRMAN PITTS: Other than that charade  
6     statement, that could very well be put into this letter,  
7     Bill, which we could draft. We could draft a letter --

8                   MR. LOCKETT: We'll be glad to work with  
9     Dr. Glantz.

10                  CHAIRMAN PITTS: -- without the charade part.

11                  DR. FROINES: I don't mean to be the right  
12     wing.

13                  DR. GLANTZ: A new role.

14                  DR. FROINES: I love the position you stake  
15     out on this one.

16                  DR. GLANTZ: Well, you haven't had to go to  
17     all these meetings with these people. As you remember a  
18     long time ago, I was going to sort of encourage them to be  
19     cooperative. My diplomacy skills totally failed.

20                  DR. FROINES: I just had a different question.  
21     We've had DBCP as an nematocide and we had EDB as an  
22     nematocide, and we've also had telone as a nematocide, and  
23     now it's my understanding that there's widespread use of  
24     methyl bromide. And methyl bromide methylates DNA and may  
25     or may not be a carcinogen. And at some point I would like

1 to know something about how is that nematocide issue being  
2 addressed because we seem to go from one carcinogen to the  
3 next. And including methyl bromide is a gas as opposed to  
4 the others, so it may disperse more readily. But that  
5 seems to me to be an issue which has been going on for at  
6 least 10 or so longer years. It would be worth knowing.

7 DR. SEIBER: Yes, I think methyl bromide is  
8 also harder to detect at low levels, so that detection  
9 limit is fairly high, and that has an impact also on what  
10 kind of an assessment you can do. Because you get a lot of  
11 zeros with methyl bromide simply because the detection  
12 limit is so high.

13 CHAIRMAN PITTS: Would you also put in  
14 metam-sodium then, isothio cyanate? Well, isn't that being  
15 used? Now, wait a minute, just out of curiosity, this is  
16 just an interesting question, that's the saga of the  
17 Sacramento River, right?

18 DR. FROINES: Methyl bromide and metam-sodium  
19 are the two replacements.

20 CHAIRMAN PITTS: That's right. It's a  
21 replacement, precisely.

22 DR. GLANTZ: Well, you know, I had written up  
23 a letter around the first of the year that I never sent to  
24 Sally Tanner saying, well, another year has gone by and we  
25 still haven't seen a pesticide. Maybe I should send it.

1 DR. SEIBER: Jim, I think it would be real  
2 useful to have Mr. Wells -- is that the gentleman's name?

3 MR. LOCKETT: Yes.

4 DR. SEIBER: -- up here and explain this and  
5 answer questions just like was raised here. And we might  
6 also want to consider down the line a workshop on  
7 pesticides in air and exposures from pesticides. Because  
8 you know, when you talk about pesticides you go from methyl  
9 bromide up to paraquat, a tremendous span there.

10 CHAIRMAN PITTS: That suggestion, I can see  
11 beams and nods around the table, I think we should proceed  
12 with that. Could we go ahead and discuss that with you,  
13 Jim?

14 DR. GLANTZ: Yes, perhaps we could have our  
15 own workshop and come up with our own list.

16 CHAIRMAN PITTS: Sure.

17 DR. GLANTZ: Could we also request that the  
18 director of this office come and not send some low-level  
19 person obscure and unnamed which has been the tradition.

20 DR. FROINES: That's like Bill Clinton's wife  
21 talking about women staying home and baking cookies, you  
22 know, some low-level person. I mean --

23 DR. GLANTZ: Well, but what happens is in the  
24 past they always send some very nice, well-meaning staff  
25 person to come and get yelled at, and it's a person who has

1 no authority to do anything.

2 MR. LOCKETT: We'll work with you on the  
3 draft.

4 So May 21 is the next meeting?

5 CHAIRMAN PITTS: Is it agreed then? That was  
6 in our calendars, Lane very efficiently got us nailed, so  
7 it will be the 21st. But we will now not have the meeting,  
8 we can cancel the meeting that was on the --

9 MR. LOCKETT: April 14.

10 CHAIRMAN PITTS: April 14th.

11 MR. LOCKETT: And the May 21 will be in  
12 Northern California.

13 CHAIRMAN PITTS: And May 21 is north. Agreed?

14 DR. BYUS: The only problem with that meeting,  
15 I believe it's the same week as the AACR meetings in San  
16 Diego, so now by switching it back up north it might be  
17 harder for me to get there. I'm going to go to the cancer  
18 meetings in San Diego. But please don't let that  
19 interfere.

20 CHAIRMAN PITTS: It might be a fun meeting.  
21 It sounds like it will be interesting.

22 DR. BYUS: No, I know it does. But I'll fly.

23 CHAIRMAN PITTS: We'll fly you up and back if  
24 we have to. If you're down in San Diego, take it. There's  
25 an airport close by. Landing is no fun though, right?

1       Coming into San Diego and that landing is always a thrill.

2               DR. BECKER: Is there an SRP meeting on June  
3       2nd?

4               CHAIRMAN PITTS: No, no. No, there's no  
5       meeting June 2nd.

6               And as far as I'm concerned, Bill, we're  
7       looking at our calenders, we're meeting May 21st.

8               MR. LOCKETT: Right.

9               CHAIRMAN PITTS: June, that was floated by at  
10      one point.

11              MR. LOCKETT: Sixteen turned out to be the  
12      next best possible date.

13              CHAIRMAN PITTS: Okay, June 16.

14              MR. LOCKETT: Oh, but that was only because  
15      Dr. Byus --

16              DR. GLANTZ: But we won't have anything on the  
17      agenda though.

18              MR. LOCKETT: No, we don't have anything on  
19      the agenda.

20              CHAIRMAN PITTS: Well, if there's nothing on  
21      the agenda there's no point in having this.

22              MR. LOCKETT: And Dr. Byus is not available,  
23      so that was it. There was no date in June when everybody  
24      was available. So the least, or to put it the other way,  
25      the most people could come was on the 16th or 18th.

1                   CHAIRMAN PITTS: But is there a need for a  
2 meeting in June if we have this May meeting? Would it not  
3 be better to wait?

4                   MR. LOCKETT: Yes, it sounds like we won't  
5 need one.

6                   CHAIRMAN PITTS: Say August, which would be a  
7 reasonable time because at that time we should have  
8 acetaldehyde, because that basically would be --

9                   MS. SHIROMA: I don't think we'll be ready by  
10 August because we'll probably hold the workshop itself in  
11 June, and then we need time to re-compile the document, go  
12 out for a second comment period, so I think August would be  
13 too soon.

14                  CHAIRMAN PITTS: Would it be feasible to  
15 simply say let's have the May meeting, we'll have the  
16 meeting in May, see what subjects for discussion come up,  
17 because there may be a number of agenda items that are  
18 worth discussing that will arise in the May meeting, and  
19 then we can formulate those and then decide.

20                  MR. LOCKETT: And then we will poll.

21                  CHAIRMAN PITTS: Then we'll poll the members  
22 and see what we'd like to have on the agenda. Okay? Is  
23 that fair enough?

24                  MR. LOCKETT: Fine.

25                  CHAIRMAN PITTS: Are there any other items for



BEFORE THE SCIENTIFIC REVIEW PANEL  
ON TOXIC AIR CONTAMINANTS

IN THE MATTER OF THE )  
IDENTIFICATION OF )  
1,3-BUTADIENE AS A )  
TOXIC AIR CONTAMINANT )

TRANSCRIPT OF PROCEEDINGS

Thursday, March 19, 1992

Arnold and Mabel Beckman Center  
National Academy of Science Building  
Irvine, California

Reported by: Diane L. Errick

## APPEARANCES

## SCIENTIFIC REVIEW PANEL

Dr. Charles Becker  
Dr. Craig Byus  
Dr. Thomas Davis  
Dr. Gary Friedman  
Dr. John Froines  
Dr. Stanton Glantz  
Dr. James Pitts - Chairman  
Dr. James N. Seiber  
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Dr. Melanie Marty  
Dr. Lauren Zeiss

1 discussion?

2 DR. FROINES: Is the meeting going to be in  
3 San Francisco though in May?

4 CHAIRMAN PITTS: Oh, yes, it's north, yes,  
5 sir. Yes, sir, it's north.

6 DR. GLANTZ: What about the ETS lead?

7 CHAIRMAN PITTS: Pardon me?

8 DR. GLANTZ: The ETS lead person.

9 CHAIRMAN PITTS: Oh, the question, yes, there  
10 is a question of the lead person has to be established for  
11 ETS; is that right?

12 MR. LOCKETT: Yes.

13 CHAIRMAN PITTS: All right.

14 MR. LOCKETT: The Chairman normally does that.

15 CHAIRMAN PITTS: The Chairman normally points  
16 the finger at the individual, okay. Well, I would -- and  
17 at this particular time, is that the time appropriate?

18 MR. LOCKETT: Fine.

19 CHAIRMAN PITTS: Well, can I -- okay. I  
20 hesitate --

21 MR. LOCKETT: As long as you've got a full  
22 panel.

23 CHAIRMAN PITTS: I was going to ask -- I'm not  
24 going to ask for volunteers necessarily, but I've given  
25 some thought to this. I would be prepared to ask perhaps,

1 Dr. Becker, would you be prepared to take on, it's a  
2 daunting task, but you're an A player and certainly in the  
3 game.

4 DR. FROINES: What about Stan?

5 CHAIRMAN PITTS: Pardon? Well, I would, the  
6 question, it's a fair question, what about Stan? And if  
7 Stan would be willing to do so, that's fair enough. We've  
8 talked about this. It may be the Chairman's position of  
9 this, actually I think that it might be more, the debate  
10 might be actually more effective if Stan were able to come  
11 in, you're chair and Stan could put his comments in from  
12 the perspective not as the lead person but in fact as one  
13 of the members of the Panel who is the expert. And I think  
14 this might be more effective all the way around. It's  
15 going to be a touchy subject. And if you'd be prepared to  
16 do this, Chuck, I think we'd appreciate it.

17 DR. BECKER: I'm prepared to do that because  
18 I'm interested in it.

19 CHAIRMAN PITTS: Okay.

20 DR. BECKER: But I would certainly defer to  
21 any of the other Panel Members. Maybe there is someone  
22 else who would prefer to take the lead.

23 CHAIRMAN PITTS: Would anyone else be  
24 interested in this?

25 DR. BECKER: I am going to be the one on lead,

1       because I've already reviewed that.

2               CHAIRMAN PITTS: That's another, yes.

3               DR. FROINES: That's a very good strategy.

4               DR. GLANTZ: Huh?

5               DR. FROINES: You know, if you get very  
6       outspoken and therefore you get to be as the expert and not  
7       as the lead, that's a good trick.

8               DR. GLANTZ: What is this? What? Run that by  
9       again.

10              DR. FROINES: Never mind, I don't want you to  
11      get smarter.

12              CHAIRMAN PITTS: That's okay.

13              Now, we also need a Part A on the exposure  
14      side, and that would be either one of the two Jims.

15              If you'd be prepared to take that, fine. If  
16      you prefer that I take it, I would. It's up to you.

17              DR. SEIBER: What was the timetable on that?

18              CHAIRMAN PITTS: Where are we on the  
19      timetable?

20              MR. LOCKETT: Well, they're working on it I  
21      think already or starting very soon. But it's going to  
22      take a while, so the timetable is summer or later.

23              DR. GLANTZ: Could I make a suggestion about  
24      the Part A. ETS is different I think than a lot of the  
25      kind of pollutants we've been dealing with so far. And in

1 order to make more work for Dr. Becker, I think at this  
2 point we could simply have one person appointed, and then  
3 as the report takes shape we could look and see if there's  
4 a need for a specific sort of Part A lead. You don't think  
5 so? Because there's a lot of it -- well, I rescind that.  
6 We should do it in the standard way. I nominate you.

7 CHAIRMAN PITTS: Thanks.

8 DR. GLANTZ: You're welcome.

9 CHAIRMAN PITTS: I would indicate to Jim also  
10 that either way, either if I were to accept it then I'd  
11 expect to get some input from you, and if you were to  
12 accept it I would give some input back.

13 I think you've raised a point, it is a very  
14 different system. You now have, it's very much going to be  
15 like diesel, this is a combination, it's combined. We have  
16 a whole -- and diesel has hundreds of compounds in there,  
17 at least 50 or 100, that may be toxic. It's a, what's the  
18 term I want, a complex mixture.

19 And you deal with complex mixtures and  
20 particulates and droplets; I'm more of the gas phase chap.  
21 And so we'd work together on this. And if you'd care to be  
22 lead, fine, I'll work with you. If you'd prefer me to do  
23 it, either way.

24 DR. SEIBER: I'd prefer to be pinch-hitter and  
25 let you take the lead.

1 CHAIRMAN PITTS: Okay, that's final. I'll  
2 take Part A then. You're the designated hitter then.

3 DR. FROINES: Can I ask you, do you have a  
4 list of who is who?

5 MR. LOCKETT: Yes.

6 DR. FROINES: Do you have it with you?

7 CHAIRMAN PITTS: You mean for future  
8 documents?

9 DR. FROINES: For the documents.

10 MR. LOCKETT: I had it with me because Bruce  
11 was here, but I don't know if I have it in my case. Just a  
12 second.

13 DR. FROINES: Do you know who is who? Because  
14 I frankly don't know what I am. Maybe we should poll the  
15 meeting.

16 CHAIRMAN PITTS: The lunch is ready, but let's  
17 finish this off, and then if there are other items. But I  
18 want to announce there is a lunch.

19 MS. DENTON: I just wanted to mention that,  
20 John, you are the PAH person. So you're --

21 MS. SHIROMA: BAP.

22 MS. DENTON: BAP and diesel exhaust. So those  
23 are the ones that are coming up for you.

24 MS. SHIROMA: Probably towards the latter part  
25 of the summer.

1 CHAIRMAN PITTS: Pardon?

2 MS. SHIROMA: BAP and diesel exhaust,  
3 Dr. Froines is lead on the Part B.

4 CHAIRMAN PITTS: That's fine. I'd be happy to  
5 take lead on Part A because that's sort of my bag.

6 MS. DENTON: Right, you are. You are,  
7 Dr. Pitts.

8 CHAIRMAN PITTS: Yes, I am, yes, that's fine.  
9 As long as you include nitro BAP. And also the  
10 nitrocoumarins.

11 By the way, just as a matter of fact we  
12 discovered that, take phenanthrene, right, naphthalene and  
13 this phenanthrene now, and if you put it in ambient air or  
14 actually in synthetic air you get a coumarin derivative.  
15 You stick a nitro on it, it's incredibly, incredibly active  
16 in the Ames assay. And hundreds of thousands of  
17 activities, units, are out there. Roger Atkinson  
18 identified this. It's kind of an interesting gap.

19 Up to now the mutagenicity in ambient air, you  
20 could find 10 percent, and it's in smoke now too, you find  
21 10 percent maybe, added up. And people wonder, what's the  
22 other 90? This has been wondered since about 1980. And  
23 this really is interesting. The phenanthrene is out there;  
24 in some way or shape or form it oxidizes to this O C double  
25 bond O with an NO2 on it.



1 DR. SEIBER: That's real interesting.

2 CHAIRMAN PITTS: That just came out. It just  
3 came out in ES&T as a communication to the editor. And an  
4 interesting medical point of view too.

5 DR. SEIBER: That's real interesting because  
6 the plant-derived coumarins are known mutagens and  
7 carcinogens. Many are proven animal carcinogens.

8 CHAIRMAN PITTS: Well, actually we identified,  
9 I went back and looked, in '82 our group had a small paper  
10 on the fact that you see the analog of the coumarin, we  
11 identified that in diesel exhaust in ambient air. The  
12 non-nitro was there, benzocoumarin, for example. So this  
13 typically, you've got the 4 5 double bond, I mean, you've  
14 got the 4 5 double bond in that position, then you can  
15 perhaps for example hypoxidize it then hydrolyze it, then  
16 you could rearrange to the lactone, and then maybe, maybe  
17 nitrate then. I don't know, I haven't talked to Roger.  
18 Nitrate first and then it rearranges. But it's a real  
19 breakthrough in terms of ambient mutagenicity, a huge  
20 breakthrough.

21 DR. FROINES: We're currently publishing our  
22 data now --

23 THE COURT REPORTER: Excuse me.

24 DR. GLANTZ: You know, we should probably  
25 adjourn.

1 CHAIRMAN PITTS: Oh, this is sort of off the  
2 record.

3 DR. GLANTZ: I move we adjourn.

4 CHAIRMAN PITTS: All right, let's adjourn. I  
5 just wanted to throw a little science into the end of this.

6

7 (Whereupon, at the hour of 1:00 p.m., the  
8 hearing was concluded.)

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## CERTIFICATION

STATE OF CALIFORNIA )  
COUNTY OF VENTURA ) SS.

I, DIANE L. ERRICK, hereby certify that the foregoing pages 1 through 106, inclusive, are a true and correct verbatim transcript of the proceedings as reported by me.

WITNESS my hand this 25th day of March, 1992, Ventura, California.

*Diane L. Errick*  
DIANE L. ERRICK